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ABSTRACT

The appendix contains papers, reports, and other materials that were reviewed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research during its deliberations on research involving children. Entries include the following titles and authors: "Research Involving Children" (Survey Research Center); "Law of Informed Consent in Human Experimentation--Children" (G. Annas, et al.); "The Ethics of Non-Therapeutic Clinical Research on Children" and "Proxy Consent in the Medical Context--The Infant as Person" (W. Bartholome); "The Competence and Freedom of Children to Make Choices Regarding Participation in Biomedical and Behavioral Research" (L. Ferguson); "Rights, Duties, and Experimentation on Children--A Critical Response to Worsfold and Bartholome" (S. Hauerwas); "Children and the Institutionalized Mentally Infirm" (H. Foster and C. Kyukendall); "Resolution and Recommendations of the Workshop on Children", "Responsibility in Investigations on Human Subjects" (from the Report of the British Medical Research Council); "Ethical Standards for Research with Children" (from the Society for Research Development); "Protection of Human Subjects, Policies and Procedures" (from the Department of Health, Education, and Welfare); and "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations" (from the American Academy of Pediatrics, Committee on Drugs). (SBH)

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APPENDIX
TO
REPORT AND
RECOMMENDATIONS

Research Involving Children

THE NATIONAL
COMMISSION FOR
THE PROTECTION OF
HUMAN SUBJECTS
OF BIOMEDICAL
AND BEHAVIORAL
RESEARCH

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This Appendix contains papers, reports and other materials that were reviewed by the Commission during its deliberations on research involving children.

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RESEARCH INVOLVING CHILDREN

Survey Research Center
University of Michigan
Arnold S. Tannenbaum, Ph.D.
and Robert A. Cooke, Ph.D.,
Principal Investigators

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Research Involving Children

The data of this report have been obtained through interviews with 471 research investigators who have engaged in research involving children and with 144 children-subjects or their proxies. These projects come from our sample of 61 institutions having general assurance of compliance with DHEW regulations for protection of human subjects. The research investigators who have responded to our interviews are approximately 75 percent of the total number of such persons who were initially drawn in our sample. The representation of research investigators in our final sample corresponds reasonably well to our initial design. (A more precise statement concerning the reliability of all samples in the study will be presented in the final report.) The final sample of subjects, however, does not correspond well to our design, in part because some institutions did not allow access to subjects and some investigators were unable or unwilling to undertake the additional effort necessary to arrange our contact with subjects. We cannot claim, therefore, to have a representative sample of subjects or proxies. We nonetheless present data in this report obtained from subjects or proxies in order to illustrate the reactions of some of these persons to the research in which they participated.

Projects differ from one another in the percent of subjects who were children. This report presents data furnished by investigators for all projects in which at least 25 percent of the subjects were under 19 years of age. Twenty eight percent of all of the projects that passed through our sample of IRB's during the period of July 1, 1974 to June 30, 1975 met this criterion (Table I.1). In addition, we discuss data from all interviews taken with children or their proxies, not just those involved in projects in which at least 25 percent of the subjects were under age 19.

The report is divided into seven sections. The first describes the types of research involving children in a variety of institutional settings. The second concerns selection of subjects. The third section describes the risks and benefits of research as reported by researchers. The fourth section discusses informed consent and the fifth reviews the comprehensiveness and comprehensibility of consent forms used in research involving children. The sixth section discusses subjects' and proxies' perceptions of the research process. A seventh section presents the suggestions and opinions of investigators and some subjects/proxies. Accompanying the report is an appendix which presents a large number of tables, most of which are summarized in the report.

Summary of Findings

Projects that included 25 percent or more children represent about a quarter of all of the research that passed through review boards between July 1974 and June 1975. Fourteen percent of this research was reviewed by boards at children's hospitals and 52 percent by boards at medical schools, hospitals (other than children's) and other biomedical research centers. The remaining 34 percent was reviewed at universities (not including medical schools) and, to a lesser extent, at institutions for the mentally infirm and at behavioral research institutions.

Approximately half of the projects involving children were primarily biomedical. Behavioral research accounts for about 40 percent of the research, and the remaining small percentage entailed secondary analyses.

Patients served as subjects in most of the projects reviewed at children's hospitals, medical schools, and other biomedical institutions. Patients also participated in about a third of the projects reviewed at universities (without medical schools) and at other behavioral research centers. In a large majority of projects, investigators reported that subjects were selected because of a specific condition or characterisitic.

Most of the research, according to investigators, was designed primarily to benefit subjects directly or to benefit in the future persons with psychological or medical conditions similar to those of the subjects. Almost a third of the projects were designed primarily for other purposes such as contributing to scientific knowledge. In approximately 70 percent of this latter group of projects, subjects were selected because they had a particular condition or characteristic.

According to investigators, the changes most frequently requested by review committees concerned procedures for obtaining consent, occurring in about a quarter of the projects. Consent procedures for secondary analyses were more likely to elicit recommendations for change than were procedures for other types of studies, the more frequent change here being the requirement that written consent be obtained from subjects.

Oral and/or written consent was obtained in almost all projects in which children participated. Almost all of the projects from children's hospitals and about two thirds at other places employed proxy consent. Parents, relatives, and legal guardians were the most frequent proxies. Most investigators felt that proxy consent protected subjects "very well" or "fairly well," but a small percent indicated otherwise.

Written consent forms were used in almost all research in children's hospitals and in about three quarters of the projects in other institutions. The purpose and procedures of the research were mentioned in most forms. Risks were mentioned in most but not all projects that investigators indicated entailed some risk. Other elements were mentioned infrequently. An analysis of the readability of the consent forms suggests that most are at a difficult reading level.

We cannot claim to have a representative sample of subjects and proxies and must therefore interpret the data from this set of respondents with caution.

Almost three quarters of the respondents reported that they were given as much information as they wanted; 19 percent said that they were given less than they wanted. Almost all said the information was clear and understandable and that the researchers were willing to answer any questions, but 17 percent reported that they did not understand, before the subject's participation actually began, that research was to be involved. The most frequent reason given for participation in the project was some anticipated medical or psychological benefit. Ninety-six percent of the respondents reported no unexpected difficulties, and the four percent who did generally felt that these difficulties were not very serious. Sixty percent felt that the subject benefited from the research.

Investigators' attitudes toward the review boards were for the most part more favorable than unfavorable. Nonetheless, half of the investigators offered suggestions or expressed concern about problems, such as the time-consuming nature of the process and the failure of the boards to discriminate between high risk and low risk research. Approximately one third of the subjects and proxies also offered suggestions, including the need for more information about the research and more carefulness by researchers.

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Robert A. Cooke, Ph.D., Study Director

Arnold S. Tannenbaum, Ph.D., Program Director

I. Types of Research (Tables I.2-I.9)

Approximately half of the research projects involving children were primarily biomedical, most frequently entailing the administration of drugs or the clinical evaluation of bodily fluids or tissues (Tables I.2 and I.3). Behavioral research, on the other hand, accounted for approximately 40 percent of the research involving children. About a fifth of this behavioral research entailed the study of an intervention of some kind, such as social or psychological therapy, behavior modification, or educational innovations. The behavioral research which did not entail the study of such interventions included primarily psychological or educational testing, interviews or questionnaires, or behavioral observation. Secondary analyses represented the remaining small fraction (about three percent) of research on children. Some of these studies involved the evaluation of bodily fluids or tissues obtained for purposes other than these studies or new analyses of data that had been previously collected.

Investigators reported that about half of the drug studies on children were done under an Investigational New Drug Application (INDA) from the FDA. Relatively few of these projects were Phase I or Phase II studies, according to investigators, but about half of the investigators whose studies involved the administration of drugs or chemical agents indicated that they did not know whether or not their projects fit one or another of the FDA phase categories of drug testing (Table I.4). In 37 percent of the drug projects, investigators indicated that the drug administration would have occurred even if subjects were not participating in the project. Drugs were administered primarily by injection in slightly more than half of the drug studies, while oral administration was the mode in 43 percent of these projects.

The studies that entailed the analysis of bodily fluids included, in over 90 percent of the cases, the examination of blood. Urine was also obtained in about half of the studies in which children's bodily fluids were examined, and in over 90 percent of these cases the urine was freely voided. According to investigators, the procedures used to obtain these fluids would have been employed in about half of the cases even if the research had not been conducted.

Research involving children was reviewed by IRB's in a variety of types of institutions. Children's hospitals accounted for 14 percent of this research (Table I.5). The largest portion of research involving children (52 percent) was accounted for by other biomedical research institutions, mainly medical schools (and universities that share a review committee with medical schools) but also by hospitals and a very small number of other instituti such as nursing and dental schools and biomedical research institutions. The remaining research (34 percent) was reviewed by committees located mainly at universities (but not by committees which review medical school research), with some reviewed at institutions for the mentally infirm and at behavioral research institutes.

Most of the research (79 percent) reviewed at children's hospitals was biomedical, involving primarily the administration of a drug, chemical agent, or blood or entailing the clinical evaluation of bodily fluids or tissues (Table I.6). Research reviewed at other biomedical research institutions was also primarily biomedical, although not with such preponderance as research reviewed at children's hospitals. Most of the research (68 percent) reviewed at the remaining set of institutions, however, was behavioral.

According to investigators, review boards formally required a number of actions from researchers, primarily by requesting more information about the research or by asking for changes in the consent forms and procedures. Review boards wanted more information in approximately 40 percent of the biomedical and behavioral intervention studies and they requested modifications in consent forms in 40 percent of the secondary analyses (Table I.7). Other requested modifications, such as those in scientific design, subject selection, risks, discomforts, and confidentiality, occurred relatively infrequently.

Changes also resulted from informal discussion between researchers and board members prior to the submission of the proposal. About a third of the investigators reported such discussion (Table I.8). Investigators reported making modifications in over half of the cases where such discussions occurred (data not shown).

Research design features like blind methods, randomization, cross-over designs, and placebo administration occurred relatively infrequently among these studies (Table I.9).

II. Selection of Research Subjects (Tables II.1 to II.9)

Review committee emphasis on subject selection. Subject selection was not an area of major IRB involvement, according to investigators. IRB's by and large accepted investigators' plans for subject selection, although changes were required for 10 percent of the proposals in children's hospitals (Table II.1). While these changes usually limited who could be involved in the research, investigators in only a few cases indicated that the purpose was to exclude high-risk subjects.

Characteristics of research subjects. Patients served as subjects in 84 percent of the projects reviewed by IRB's in children's hospitals, in 72 percent of the projects in other biomedical institutions, and in 30 percent of the projects in other institutions. Subjects with no specific characteristic other than age were involved in 20 percent of the projects in children's hospitals, in 35 percent of the projects in other biomedical institutions, and in 49 percent of the projects in other institutions (Tables II.2, II.3). Adults, such as staff and college students, also served as subjects along with children in some projects, particularly in non-biomedical settings, where they were involved in 36 percent of the projects. Subjects in most projects were either the investigator's own patients, referrals from other physicians or professionals, or from an institutional population to which the investigator had professional ties (Tables II.4, II.5).

In a large majority of projects, investigators reported that subjects were selected because of a specific condition or characteristic (Tables II.6, II.7). The presence of a specific disease or medical condition was a selection criterion in over 85 percent of the projects reviewed by IRB's in both children's hospitals and other biomedical institutions, and in 38 percent of the projects in other institutions. Among these latter projects, mental disorders were the primary medical condition used in the selection of subjects. The presence of a behavioral problem was used to select subjects for 11 percent of the projects in non-biomedical institutions (Tables II.8, II.9).

Demographic characteristics were used to select subjects in 29 percent of children's hospital projects, 20 percent of the projects at other biomedical institutions, and 57 percent of the projects at other institutions. At each type of institution, age was a selection criterion for a substantial number of projects. Also, the subject's educational situation was a factor in 17 percent of the projects in other institutions.

III. Risks and Benefits of Research (Tables III.1-III.21)

Research which, according to investigators, was designed primarily to benefit the subjects directly accounts for approximately one fourth of all projects involving children (Table III.1). Another quarter of the projects, while not primarily intended to benefit the subjects directly, were intended to benefit in the future persons with psychological or medical conditions similar to those of the subjects. An additional 32 percent of the projects had other purposes, according to investigators, including contributions to scientific knowledge. We divided this latter group into two parts which include, first, those projects in which the subjects were selected specifically because of a particular condition, characteristic, or illness (23 percent) and, second, those in which subjects were not selected for a particular condition (9 percent). (Eighteen percent of the projects could not be classified into any of the above categories because investigators did not answer both of the appropriate questions.)

The primary purpose of most biomedical research involving children was reported to be to benefit either the subjects (35 percent) or others with a similar condition (30 percent) (Tables III.2 and III.3). Studies of behavioral interventions were even more likely to be reported as intended primarily to benefit subjects (46 percent), while 24 percent of such studies were intended to benefit others with a similar condition. Other behavioral research, as well as studies involving secondary analysis, were much less likely to be primarily intended to benefit either subjects or persons with similar conditions.

Investigator estimates of risks and benefits for research designed primarily to benefit subjects. Each investigator was asked about the probability of different types of risks and benefits for subjects "in terms of your understanding of the risks and benefits at the time the study began." Investigators for a substantial majority of the projects designed primarily to benefit subjects estimated that their research would have a medium or high probability of medical or psychological benefit (Table III.4). None of these investigators estimated as much as a medium or high probability of serious risk, although about half of them reported a low or very low probability of minor psychological or minor medical complications. Approximately one fourth or fewer estimated a very low or low probability of serious medical complications, fatal complications, serious psychological stress or embarrassment to subjects due to breach of confidentiality. Investigators who reported such risks of serious medical or fatal complications refer to the use of procedures like manipulation of catheters, renal scans, use of experimental drugs and the use of cold. An inspection of a sample of these interviews suggests that these procedures occur with subjects whose medical condition is serious.

Risks and benefits of research intended primarily to benefit others like the subject. Most of this research is biomedical and the probabilities of benefits and risks follow a pattern similar to the research intended to benefit subjects, although fewer investigators here than above reported a probability of medical and psychological benefits (Table III.5). Furthermore, a somewhat smaller percentage of projects were reported to have risks (with the exception of minor psychological stress), and in practically all cases the probabilities were rated very low.

Risks and benefits of research conducted for other purposes (subjects selected for condition). Slightly more than a quarter of these projects are reported to have some probability of psychological or medical benefit and a medium or high probability of other benefits such as an educational and enriching experience, other personal advantages, or the experience of satisfaction from helping develop new knowledge (Table III.6). Generally lower levels of risk were reported than in previous categories; most such risks were designated as minor and of very low probability.

Risks and benefits of research conducted for other purposes (subjects not selected for condition). Some probability of medical or psychological benefit was indicated for one third of these projects; a very low or low probability of minor psychological stress was indicated for more than half of the projects (Table III.7). Only small percentages of the projects were reported to have any probability of minor medical complications, serious psychological or medical complications, or breach of confidentiality.

The distribution of benefits and risks, by type of research, appears in Tables III.8-III.11.

Present assessment of risks and benefits by purpose of research. Most investigators reported that the risks and benefits actually experienced corresponded to their pre-research estimates. Less than 10 percent of the investigators indicated that actual benefits were less than expected; substantially more indicated that the benefits were greater than expected (Table III.12). Fewer than 5 percent of the investigators reported that the risks had been greater than expected; substantially more indicated that risks were less than expected (Table III.13). Almost all investigators reported that they had been very certain or fairly certain before the study began that they knew all of the risks that the project entailed (Table III.14). In general, investigators studying behavioral interventions indicated less certainty about risks and benefits than investigators in other types of research (Tables III.15-III.17).

Very few investigators indicated that they assessed the risks to subjects as outweighing the benefits (Tables III.18-III.21). The tables also show that some assessments of risks and benefits shifted, based upon knowledge gained in the research.

Injuries or harm as a consequence of research and mechanisms of compensation. Each investigator was asked whether there had been any injuries to subjects as a result of participation in the research, without regard to whether or not there was negligence. These questions referred to unexpected problems, not customary side effects. Occurrences affecting from one to four subjects were reported in a small percentage (6 percent) of the projects intended to benefit subjects and in 2 percent of the projects intended to benefit others. Most, but not all, of these injuries were described as trivial.

Harmful effects as consequence of breach of confidentiality. No breach of confidentiality which has harmed or embarrassed subjects was reported for any type of research. Most investigators for all types of research reported having some mechanism or procedure to protect the confidentiality of subjects if names were recorded. The procedures to protect subjects' confidentiality most often mentioned were separation of names from data, limited access to data, mechanical means such as locking up the material, and not using names in publications.

IV. Informed Consent (Tables IV.1-IV.31)

Review committee action. Review committees required changes in the procedure for obtaining consent in about a fourth of the projects involving children. Changes were required most frequently (35%) in projects reviewed at children's hospitals. Many of these changes pertained to the explanatory materials to be presented to subjects or proxies. Similar changes were required, although less frequently, in projects from other institutions (Table IV.1). Protocols concerning secondary analyses were more likely to elicit a recommendation for change than were biomedical or behavioral protocols. The most frequent change in secondary analysis projects was the requirement that written consent be obtained from subjects. Among biomedical projects, additions to or other alterations of materials to be presented to subjects were the changes most frequently required (Table IV.2).

Written and oral consent. Oral and/or written consent was obtained from subjects in all projects at children's hospitals, in 88 percent of the projects at biomedical institutions, and in 92 percent of the projects at other institutions (Table IV.3). With respect to research types, oral and/or written consent was obtained from subjects in over 90 percent of biomedical, behavioral intervention, and other behavioral projects, and in 29 percent of secondary analysis projects* (Table IV.4). Reasons cited by principal investigators to explain why no consent was obtained include: (1) return of questionnaire implied consent; (2) only routine treatments or procedures were being used; (3) names of subjects were unavailable to the researcher; (4) consent was obtained elsewhere; (5) no risks to subjects were involved; and

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*The secondary analysis projects where consent was obtained involved, for example, tissue analysis where subjects were requested permission for the use of tissue.

(6) the review committee did not require that consent be obtained. Consent was usually obtained in writing (Table IV.3), and principle investigators of over 80 percent of the projects said that they provided an oral explanation of the study to subjects or their proxies (Tables IV.5, IV.6).

The consent process: who obtains consent? Investigators had either exclusive or shared responsibility for obtaining consent in the majority of the projects (Tables IV.7, IV.8). The other persons who obtained consent were most frequently on the study staff, but on several projects a person not on the study staff obtained consent. A professional colleague of the principal investigator, either on or off the study staff, was the most frequent other person to obtain consent. Less frequent were nurses, interns, students, and research assistants. (Table IV.9).

Aside from the person who obtained consent, the subject and/or the proxy, other people were present in about half the projects when consent was sought. In biomedical research generally, the other person present was usually a nurse or a member of the subject's family. (Tables IV.10, IV.11).

Gaining the participation of research subjects. We analyzed the relationship between aspects emphasized by investigators seeking consent and the purpose of the research. For those projects whose primary purpose was to benefit the subjects, this direct benefit was emphasized most frequently, although other purposes of the research were also mentioned frequently (Tables IV.12, IV.13). When the primary purpose of the study was to benefit others, that fact was most frequently given the greatest emphasis, according to investigators, although in about a third of these projects the investigators also emphasized a direct benefit to the subject.

Finally, for research with some other primary purpose, its potential benefit to others and its benefit to scientific knowledge were each emphasized in about half the cases; however, investigators reported emphasizing direct benefits to subjects for 37 percent of these projects. As was previously noted, many investigators indicated that benefits might accrue to subjects even in projects not designed primarily to benefit subjects.

When obtaining consent, principal investigators generally reported that they presented the possibility of participation as a request. However, when the primary purpose of the research was to benefit the subjects, participation was frequently described to subjects as both a recommendation and a request (Table IV.14).

Investigators of some projects did not reveal all information to subjects. Information was withheld most frequently in behavioral projects and at institutions other than children's hospitals and biomedical institutions. The information not divulged focused most often on the purpose or specific procedures of the study, the medication or treatment being used, and possible benefits to the subject (Tables IV.15, IV.16). Most reasons for this withholding of information concerned biases that divulging could introduce in the data.

In a few projects that were behavioral or from non-biomedical institutions, subjects were told things that were not true. The aspects of false information centered around the purpose or specific procedures of the study (Tables IV.17, IV.18), and the reasons again involved fear of biasing the data.

In the vast majority of projects, subjects were not paid for participation. In the remaining projects, payments were small, usually $1 to $5, and usually occurred where the research was not designed to benefit the subject directly (Table IV.19).

Principal investigators felt that the decision to participate in the study was not difficult for subjects or proxies in the majority of projects, regardless of the purpose of the research (Table IV.20). Furthermore, projects with different purposes did not differ from one another in the extent to which prospective subjects/proxies declined to participate (Table IV.21). Some subjects/proxies declined in about one third to half of the projects.

Proxy consent. Ninety-four percent of the projects from children's hospitals, 69 percent from biomedical institutions, and 67 percent from other institutions used proxy consent (Table IV.22). Similarly, 79 percent of biomedical projects, 64 percent of behavioral intervention projects, 69 percent of other behavioral projects, and 13 percent of secondary analysis projects involved proxy consent (Table IV.23).

In the projects where proxy consent was used, consent was obtained only from proxies twice as often as it was from subjects as well as proxies. The most frequent criterion for determining whether proxy consent would be used was the subject's age.* Less frequent criteria were the intellect and the degree of illness of the subjects, in that order (Tables IV.24, IV.25).

Parents, relatives, or legal guardians of the subjects were the most frequently used proxies. Institutional representatives served as proxies in five percent of projects in children's hospitals and three percent in other institutions, whereas courts fulfilled a proxy function in six percent of projects from other institutions, and only in non-biomedical projects (Tables IV.26, IV.27). Approval for participation was obtained from the subject's physician in a majority of cases when the subject was the patient of someone other than the principal investigator.

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*The age above which no proxy consent was obtained ranged from 4 years, in rare cases, to 21 years, more frequently. The median age above which no proxy consent was obtained was 18 years. The age below which consent was not obtained from the subject as well as the proxy ranged from 1 year to 21 years. The median age below which consent was not obtained from the subject as well as the proxy was 7 years.

A majority of investigators reported that subjects for whom proxy consent was obtained were rarely or never reluctant to participate. In children's hospitals, where the greatest reluctance was encountered, approximately 20 percent of investigators reported that their subjects were sometimes or often reluctant to participate (Table IV.28). Similarly, biomedical projects more than other types were likely to have reluctant subjects, according to the reports of investigators (Tables IV.29). Investigators indicated further that when such instances occurred, the most frequent outcomes were (1) that the subject did not participate, or (2) an attempt was made to persuade the subject. Investigators rarely reported that subjects had no choice but to participate.

Most investigators reported that proxy consent protected subjects "very well" or "fairly well". In three percent of projects from children's hospitals, 7 percent from biomedical institutions, and 14 percent from other institutions, investigators indicated otherwise (Table IV.30). The main explanations given for the inadequacy of proxy consent were: (1) where only proxy consent is used, subjects may not be able to decide themselves whether or not they wish to participate in the research; (2) the proxy may not be able to understand the research; and (3) the proxy may not care about protecting the rights of the subject.

V. Consent Forms (Tables V.1-V.12)

As was shown in Table IV.3, written consent forms were used in almost all research in children's hospitals and in about three quarters of the projects in the other institutions. At least two thirds of these forms were developed specifically for a particular study; others were based on a standardized form provided by the institution (Table V.1). About 70 percent of the forms contained less than 300 words, and these are designated as "short" forms in our analyses (Table V.2).

In most projects, subjects/proxies were not given a copy of the form to keep (Table V.3).

Content of consent forms. Consent forms contain information about a wide variety of topics, as might be expected in view of the variety of research being conducted. To increase comparability of consent forms, an index of completeness was constructed. This index represents the extent to which a consent form covers each of the following: (1) the purpose of the research, (2) procedures involved, (3) the risks, (4) the benefits, (5) a statement that subjects are free to withdraw from the research, and (6) an invitation to subjects to ask questions about participation. (See Table V.4 and the accompanying explanation for more information about this index.)

The index shows only 20 percent of the consent forms from children's hospitals and other biomedical institutions, and only five percent of the forms from other types of institutions, to be complete or nearly so (Table V.4). Some elements were present more often than others in consent forms. Purpose and procedures are mentioned in two thirds or more of the forms. Risks are mentioned or described in detail in two thirds of the forms from children's hospitals, in half of the forms from other biomedical institutions, and in less than a quarter of the forms used in the other institutions (Table V.5).

Mentions of benefits (or the absence of benefits), freedom to withdraw, and opportunity to ask questions appear less often.

It might be expected that alternative treatments would be mentioned in consent forms used in projects designed primarily to benefit subjects; however, this occurs only rarely (Table V.6). Similarly, it might be expected that consent forms in studies designated by investigators as containing "experimental" elements would contain words indicating that fact; this occurs infrequently, except in non-biomedical institutions (Table V.7). Thirty-eight percent of the projects involving placeboes mentioned placeboes in their consent forms. Fourteen percent of the projects in which some information would be withheld from subjects mentioned this in their consent forms and statements. Eight percent of the projects in which subjects were assigned to one of several treatments or procedures being studied or compared mentioned this in their consent forms. One quarter of the projects intended to benefit subjects mentioned benefits in their consent forms; 12 percent of the projects not intending to benefit subjects indicated benefits to subjects in their consent fo The frequency with which other topics of possible interest appear in consent forms is shown in Table V.8.

Readability of consent forms. We used the Flesch technique to assess readability of consent forms. The details of this technique are described in a note following Table V.12. Short consent forms were given an overall readability score while long forms were given a score for each of three content areas: purpose, procedures, and risks.

Tables V.9-V.12 summarize our analysis and show that consent forms tend to be difficult to read.

Medical and technical terms comprise substantially less than five percent of the words in most consent forms. Although these terms describe important aspects of research projects, most consent forms provide very little lay explanation of their medical and technical terms, and forms that do provide lay explanations are still generally difficult to read. Furthermore, some consent forms with very few or no medical and technical terms are difficult. Thus, reading difficulty cannot be attributed solely to the percentage of medical and technical terms which appear in these forms.

Sentence structure along with length of words determines the readability score. Variations in readability are illustrated in the following examples.

An example of a "fairly easy" consent form:

I would appreciate having your child participate in the study at his school. Permission is voluntary; you may check either of the statements below. Note that even if you should grant permission, your child is still free to choose for himself whether or not to participate in the study, and also to withdraw from the study at any time.

A consent form excerpt rated "difficult" due to sentence length and structure:

We understand that telephone calls from a member of the isolation study* team will be made to our home about once weekly at a time convenient to us and that a member of the study team will visit our home to obtain nose and throat specimens for virus isolation about twice monthly at a time convenient to us.

*Not the actual name.

A consent form excerpt rated "difficult" due to medical and technical terms:

Total intravenous infusion, a therapy for providing all calorie needs entirely by intravenous means, is being compared to regular oral food ingestion in order to learn whether it will reduce undesirable side effects, especially anorexia, nausea, and vomiting, and resulting weight loss which may develop from etiotropic treatment necessitated by the metastatic nature of your child's disease.

VI. Subjects' and Proxies' Perceptions of Research (no tables)

Subjects were approached through principal investigators who were willing to write to their subjects on our behalf, asking them to return to us a stamped card if they were willing to be contacted. It was only through the cards that were returned that we learned the names of subjects. Some institutions did not allow this access to subjects, and some investigators were unable or unwilling to contact their subjects for us. However, many investigators did participate in the procedure, enabling us to contact and interview by phone 31 children and 113 proxies. This sample, of course, is not representative in any statistical sense. For this reason, and because the interviews often took place months after a subject's participation in research, the data should be treated cautiously.

The data provided by our "sample" of proxies and children-subjects indicate that most of them felt that they were provided with adequate information about the research project. Seventy-five percent of the respondents remembered that they signed a consent form and, of those who did not remember, all but five recalled that they gave their permission orally. Nonetheless, 17 percent of the respondents reported that they did not understand, before their participation actually began, that the subject was to be involved in research.

Although most respondents said that they were given as much information about the study as they wanted, 19 percent reported that they were given less information than they wanted. Approximately 90 percent of our respondents felt that the information they were given was clear and understandable. Those who reported that the information was not completely clear were asked, "In what way was it not clear?" The purpose of the research was unclear to three respondents; one respondent was unclear about the procedures to be used and another said that he was not clear about the type of drug to be used. A very few respondents reported that the information they were given was unclear due to its technical language or lack of detail.

Sixty-five percent of the respondents said that they asked the researchers questions about the study or the subject's participation in the study. These questions most frequently concerned the procedures to be followed, the discomforts associated with the procedures, and the risks or possible side effects which subjects might experience. Questions concerning benefits, the availability of the results of the study, and the purpose of the research were also reported. Some respondents were interested in and asked the researchers about the drugs to be used, the amount of time the subject would be involved in the research, the nature of the subject's disease or condition, previous research, and the subject's "performance" on the test (in educational and psychological studies). Almost all of the respondents said that the researchers were willing to answer any questions they might have; but five respondents felt that the people connected with the study were unwilling to answer questions. Ninety percent of the respondents felt that the information they had been given was correct and accurate. Among those who did not see the information as accurate, three reported inaccuracies regarding procedures and one respondent felt that the information concerning side effects was incorrect.

Proxies reported in more than one out of three cases that someone connected with the study talked to the subject about what was going to be done. Almost half of the proxies felt that the subject understood, either very well or fairly well, what participating in the study would be like. Some subjects were not apprised of what was going to happen and apparently did not understand what participation in the study would involve. Approximately half of the subjects in our sample were less than six years old.

The proxies and subjects who were interviewed apparently had few problems deciding whether or not they (or the person for whom they gave consent) should participate in the projects. Seventy-five percent of the respondents said that the decision was "not at all" difficult and only four percent said that it was a very difficult decision. Consistent with this finding, proxies and subjects cited many reasons for participating and very few reasons for not participating in the research. The most frequently mentioned reason in favor of participation was that involvement in the research might help the subject; almost one quarter of the respondents mentioned educational, psychological, or medical benefits which might result from participation. The next most important reasons for participation were to help other people with similar conditions and to help research or science. Other reasons given for participating included respondent's interest in learning how the subject would perform on a psychological or educational test and the desire to "help" the particular study because it seemed worthwhile. Very few people cited financial reimbursement (one percent) or physician/researcher recommendations (three percent) as the most important reason for participating, and no respondents said that free care or services was the most important factor in their decision. Ninety-four percent of the respondents offered no reasons for not participating. The few people who considered not participating mentioned the unpleasant procedures, the health of the subject, or a fear of side effects.

A series of interview items focusing on expected risks and benefits generated responses similar to those reported above. Sixty-eight percent of the proxies (or subjects) thought that there might be some possibility of benefit to the subject as a result of participation. Direct educational, psychological and medical benefits to the subject were mentioned most frequently. Future benefits--including preventative benefits, free check-ups and tests, and other future advantages in health care--were the second most frequently mentioned benefits. Only one respondent mentioned money as a benefit.

While the majority of respondents anticipated benefits, most of them (72 percent) expected that there was "no risk at all" of harmful effects. We asked those respondents why they saw no risk of harmful effects. In many cases, the respondents noted that the procedures which were outlined to them implied no harmful effects or that the side effects they were told about did not seem serious. Others reported that they were "told there was no risk" or that someone on the research staff explained that there was no risk. Some people felt that no risk was involved because they had confidence that nothing would be done that would cause harm or because they had faith in the good will and work of the researchers. Only a few respondents felt there were no risks because of their previous experience or the experiences of others (e.g., friends, other subjects). No respondents mentioned the consent form when explaining why they expected no risk of harmful effects. The respondents who expected at least a very slight risk of harmful effects (28 percent) mentioned side effects from drugs, internal damage, minor physical discomforts, or unpleasant emotional/psychological side effects. These risks were expected mainly because the subject/proxy was told that there was some possibility of harmful effects, because the procedures seemed to the respondent to be risky, or because of the nature of the drugs to be used.

The proxies and subjects interviewed apparently did not experience many unexpected difficulties. Ninety-six percent of the respondents reported no unexpected difficulties and the four percent who did generally felt that those difficulties were not very serious. These problems tended to be temporary and minor physical discomforts. On the other hand, the respondents expected benefits and, in general, they felt that some benefit was realized by the time the project ended. Sixty percent of the people interviewed felt that they, or the person for whom they gave consent, benefited as a result of participating in the research.

All interviewees were asked if the subject was treated with courtesy and consideration by the research staff. Ninety percent responded affirmatively, nine percent did not know or were not present during the subject's participation, and only one percent answered negatively. The 31 children who were interviewed were asked, "Was the actual experience of participating in the research better than you expected, about what you expected, or worse than you expected?". Forty-two percent of these subjects said it was better than expected and the remainder said it was as expected--no subjects said "worse than expected." Finally, respondents were asked if they would be willing to get involved in a similar study again. Seventy percent of the proxies and subjects indicated that they would be "very willing." Among those who were less than very willing, many said that their decision would depend on the nature of the study and the benefits to subjects. Others said they might be only somewhat or not very willing to get involved because of their fear of harmful effects or because of the time involved.

VII. The Attitudes and Suggestions of Investigators, Subjects, and Proxies

(Tables VII.1-VII.5)

Attitudes of investigators toward the review process. Investigators' attitudes toward review committees are, for the most part, more favorable than unfavorable (Tables VII.1-VII.3). However, a number of respondents in all types of institutions felt that the procedures caused at least some problems and particularly cited committee actions in areas not appropriate to its function and judgements made by the committee that it is not qualified to make. A fairly high percentage of investigators doing research involving children outside of children's hospitals felt that the procedures were impeding progress of research at least to some extent. Many investigators doing research on children outside of biomedical institutions also felt that the procedures were not improving the quality of research and that the procedures were an unwarranted intrusion on the investigator's autonomy.

Investigators' comments and suggestions. Many researchers expressed satisfaction with, or acceptance of, the review procedures as they are presently operating. Nonetheless, over half of the respondents did make suggestions or express concern about problems with the review process as they experienced it.

Comments of investigators fall into five major categories (Table VII.4). The first concerns "bureaucratic problems" such as the complicated nature of the review process and the adverse effects of the process in slowing and preventing research. Bureaucratic problems were mentioned by 12 percent of the investigators in children's hospitals, 16 percent of those doing research in other biomedical institutions, and 19 percent of those doing research in universities and other institutions (Table VII.4). Many complained specifically that the time-consuming nature of the process caused problems when they were trying to meet deadlines for federal grants, mentioning time periods of "six weeks to two months," "three weeks or longer," "three months," "six months," and "several weeks." One researcher discussed the complicated nature of the process, stating that the review procedure

> presents big headaches, one of which involves all the paper work. There were five or six forms, one for my records, one to the main bureau office and I don't know where the other forms go, and then some for the service board.

Some of the respondents elaborated on the consequences of these problems, stating,

> Some of the procedures at the present time have a tendency to restrict research in the United States and the restriction of research essentially ultimately means a restriction and slowing of medical progress.

and

> Bureaucrats who don't understand clinical research are making clinical investigation very difficult.

The second set of concerns, very much related to the first, reflects the feeling that parts of the review process should be abolished (mentioned by seven percent of the investigators at children's hospitals, 17 percent of those at other biomedical institutions, and 10 percent of those in the remaining set of institutions.) Many of the investigators who made such suggestions focused on differentiating between high and low risk research, proposing that review of innocuous research and of studies using materials from previously approved research be eliminated. Some also proposed that written and/or informed consent be eliminated for these studies. One respondent concerned with differentaiting high vs. low risk research stated,

> A major problem is that the regulations are applied without regard to the degree of risk to the subject so that lots of energy is wasted on trivial detail and insufficient attention is given to significant issues. Sort of throwing the baby out with the bath water.

Other respondents wishing to abolish certain aspects of the review process offered these comments,

> To have to get consent like if urine is being discarded, it's such an absurdity. It's impossible to define a greater bureaucratic absurdity. A nurse is throwing that urine into a urinal and we cannot use that urine unless we go back to the patient and ask him and he couldn't care

> less! Their name is never used in those kinds of studies--nothing is revealed. It's totally absurd.

and

> Biologic fluid to be discarded should be available for research without informed consent and review.

A third set of comments concerns the structure or authority of the committee (mentioned by about 11 percent of the investigators in the several sets of institutions). Some of these suggestions proposed changing the composition of the committee and the way it is selected. Some proposed more lay involvement, stating,

> If students are used as subjects, some students should be on the committee. Also some parents, when children are involved.

and

> On every review committee there should be a clergyman.

Others disagreed with this and wanted only professional researchers on the committee, stating,

> There's a great tendency to try to err on the extremely conservative side and appoint extremely elderly individuals, and people who have theological training and people who are not closely involved in human experimentation. Appoint younger individuals who are involved in human subject research. I really do not think those with theological training make very good decisions in the matter.

and

> Review committees have gone overboard by insisting there be lay people who haven't the foggiest knowledge of medicine.

A fourth set of suggestions concerns the need for more information and increased communication (mentioned by 15 percent, 9 percent, and 14 percent of the investigators at the three sets of institutions, respectively). Investigators stated that they wanted more guidelines in general, more information on consent forms, or more information from the review committee itself on what it wants, what actions it has taken and the reasons for these actions. Many investigators wanted more interaction between the researcher and the committee, and most had in mind either having the researcher orally present his/her protocol or having the researcher present when the committee reviews his/her protocol. Thus, one states,

> It wouldn't be a bad idea if there were more connection in person between investigator and committee. . . . If some difficulty were encountered perhaps it would be helpful to have the investigator present.

A fifth category of suggestions concerns protecting human subjects to a greater extent than is presently done (mentioned by about 10 percent of the investigators). These were mainly general comments that committees should be stricter and "tighter with accountability" and that "academicians don't police themselves very carefully." A number of respondents desired more follow-up after review to see that proposed procedures are implemented, and one suggested a way of accomplishing this,

> I think the problem is [that] it is difficult for review committees to police that all studies are being carried out as approved. A member of the review committee, preferably a lay person--so as not to offend one's colleagues and associates--should actually, without warning, check with patients who are involved in projects to be sure that the projects are being carried out as submitted to the human studies reveiw committee.

Subjects' and proxies' comments and suggestions. Approximately one third of the subjects or their proxies offered suggestions. These suggestions fall into three categories (Table VII.5). One (19 percent) concerns requests for more information about the research in general or about issues not covered by the description that was provided by the investigator of risks, benefits, and procedures. Thus, one respondent remarked,

> More should be available to people to read. People don't know the things that their doctors can do for them. Not enough information is available about who to go to to help themselves or their children. Not enough information [is] in layman's terms.

Some subjects were interested in having a copy of the results of the research upon completion of the study and a small number expressed a desire for more or better information on benefits, risks, and procedures.

A second category of suggestions (eight percent) concerns the experimenters' conduct of the research. Some subjects desired experimenters to be better organized and to perform procedures more efficiently. Others wanted experimenters to be more courteous and kind in dealing with subjects and to take more time with subjects. One such respondent commented,

> All I can think of is to get to know the children beforehand--to get them to cooperate. It would be to their best advantage.

A third, and very small, category (four percent) concerns improving the risk/benefit ratio by increasing types of care and service benefits or by reducing risks through testing more thoroughly before the experiment.

APPENDIX

Tables

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Table I.1

Distribution of Projects According to the Percent of Subjects Who Are Children (0-18 years of age)

Projects in which the following percent of subjects are children	Percent of Projects* (N= 1485)	
0%	62%	
1-14%	8	
15-24%	2	
25-49%	5	
50-74%	4	
75-100%	19	
Projects in which 25-100% of subjects are children		28 **
Total	100%	

---

[*] Based on reports of research investigators, excluding those who did not answer the question.

[**] These are the projects disucssed in the following analyses.

Table I.2

Type of Research Involving Children

	Percent of Projects (N=471)
Biomedical	47%
Behavioral intervention	8
Behavioral	33
Secondary analysis	3
No information	9
Total	100%

Table I.3

The Primary Intervention or Procedure in Each Study

	Percent of Projects (N= 471)
Biomedical	
Clinical evaluation of bodily tissues or fluids	21%
Administration of drug, chemical agent or blood products	19
Perinatal care	-*
Surgical (includes oral)	-
Exchange of bodily fluids	-
Use of diagnostic and/or therapeutic devices	5
Dental care	1
Other	1
Behavioral Intervention	
Educational intervention	2
Modification of an organization or a service delivery system	2
Behavior modification or experimentation	3
Social or psychological therapy	1
Other	-
Behavioral (other)	
Interviews-questionnaires	6
Psychological or educational testing	12
Behavioral observation	13
Interviews with patient (e.g., medical histories)	2
Secondary Analysis	
New analysis of existing data	1
Review of medical records	-
Third party study of tissue or fluids obtained for other purposes	2
No information	9
Total	100%

---

*Less than 1 percent.

Table I.4

Is this a Phase I, II, III or IV test?

	Percent of Projects (N= 471)
Phase I	-**
Phase II	1%
Phase III	4
Phase IV	2
None of these	2
Don't know	8
No answer	3
Inappropriate*	80
Total	100

---

[*] Includes other than drug administration research.

[**] Less than one percent, but more than zero.

Table I.5

Type of Institutional Committee Reviewing Research Involving Children

	Percent of Projects[*] (N= 425)
Children's hospitals	14%
Other biomedical[**]	52
Other[***]	34
Total	100%

---

[*] Excludes cases for which we do not have information about type institution.

[**] Medical schools (and universities sharing medical school IRB) (83.7%); hospitals (15.7%); schools of nursing and dentistry and biomedical research institutions (.6%)

[***] Universities (not including medical schools) (78%); institutions for the mentally infirm (18%); and behavioral research institutions (4%)

Table I.6

General Types of Research Conducted in Different Institutions (Percent of Projects)

	Type of Institution		
Type of Research	Children's Hospitals (N= 44)*	Other Biomedical (N= 231)*	Other (N= 150)*
Biomedical	79%	69%	14%
Behavioral intervention	5	5	17
Behavioral	16	20	68
Secondary analysis	0	6	1
Total	100%	100%	100%

---

* Excludes cases for which information is unavailable concerning types of research.

Table I.7

Actions Formally Required of the Investigator by the Review Board:
Types of Research (Percent of Projects)*

	Type of Research			
	Biomedical (N= 220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N= 147)	Secondary Analysis (N= 14)
More information	38%	46	29	22
Modification in consent forms and procedures	27	12	23	40
Modification in scientific design	3	6	0	0
Modification in subject selection	4	2	0	0
Modification regarding risks, discomforts	6	7	4	0
Modification regarding confidentiality	1	2	9	9
Other modifications	5	8	.5	0

---

*Percentages need not add to 100% since respondents might indicate fewer or more than one action required.

Table I. 8 -

Prior to the submission of your proposal for review by the committee, did you have any informal discussions with any committee members concerning the use of human subjects or obtaining consent?: Type of Research (Percent of Projects)

	Type of Research			
	Biomedical (N= 220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N= 147)	Secondary Analysis (N= 14)
Yes	31%	33%	31%	47%
No	67	67	68	53
No information	2	0	1	0
Total	100%	100%	100%	100%

Table I.9

The following is a list of some methods which you may be using for your study--please check as many as apply.[*]
(Percent of Projects)

	Type of Institution		
	Children's Hospitals (N= 33)**	Other Biomedical (N= 219)**	Other (N= 144)**
Single-blind method (i.e., subject does not know which study technique is being used)	12%	13%	10%
Double-blind method (i.e., neither subject nor experimenter knows which study technique is being used)	7	3	9
Different treatment or procedures assigned by random method	14	18	25
Cross-over design (treatment or procedures switched between groups during the study)	0	5	5
Placebo administration	0	2	7
None of the above	49	52	55

---

[*] Totals may add to more than 100% since respondents could check more than one method.

[**] Excludes respondents who did not answer the relevant questions.

Table II.1

Did the review committee require you to make modifications in the proposed selection of subjects for your study? If yes, what changes?
(Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Changes required	10%	1%	2%
Exclusion of some subject categories on the basis of risk	1	-	0
Change due to considerations of equity	0	0	0
Other limitations/restrictions in sample	9	-	2
No changes required	83	98	97
Don't know	7	1	1
Total	100%	100%	100%

Table II.2

Kinds of Subjects Selected: Type of Institution (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
What kinds of subjects were selected for the experimental group on your study, that is, were they from the general population or were they patients, prisoners, college students, or from some other category?			
Persons with no specific characteristic (other than age)	20%	35%	49%
"General population"**	5	12	21
Children under 18	15	23	28
Persons with specific condition, characteristic**	4	12	13
Patients	84	72	30
Children who are patients	45	11	6
Former patients**	0	0	--
Other patients**	35	57	10
Mentally retarded**	0	--	10
Mentally ill**	2	1	2
Pregnant women	2	2	2
Fetus	0	--	0
Staff, students, others	2	12	36
Professional or institutional staff	0	3	2
Other staff	0	--	4
Residents or interns	0	0	0
Medical students	0	--	0
Other students in health field	0	--	0
Other college students	0	4	24
Miscellaneous	2	5	6

---

*Totals may add to more than 100% since respondents could mention more than one kind of subject.

**Age not specified by investigator.

Table II.3

Kinds of Subjects Selected: Type of Research (Percent of Projects)*

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
What kinds of subjects were selected for the experimental group on your study, that is, were they from the general population or were they patients, prisoners, college students, or from some other category?				
Persons with no specific characteristic (other than age)	23%	56%	53%	49%
"General population"**	8	21	19	38
Children under 18	15	35	34	11
Persons with specific condition, characteristic**	7	21	15	9
Patients	81	46	33	54
Children who are patients	21	1	8	9
Former patients**	-	0	0	0
Other patients**	58	28	12	38
Mentally retarded**	1	17	5	0
Mentally ill**	0	0	4	0
Pregnant women	1	0	4	3
Fetus	0	0	0	4
Staff, students, others	11	27	30	4
Professional or institutional staff	4	2	0	0
Other staff	0	0	4	0
Residents or interns	0	0	0	0
Medical students	-	0	0	0
Other students in health field	-	0	0	0
Other college students	3	19	20	0
Miscellaneous	4	6	6	4

---

*Totals may add to more than 100% since respondents could mention more than one kind of subject.

**Age not specified by investigator.

Table II.4

Which of the following sources are used to obtain subjects for this study?: Type of Institution (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
From among own patients	36%	48%	17%
Referrals by other physicians, professionals	32	41	10
Referrals by other subjects	6	11	11
Information from records	6	11	9
Institutional population via professional access	30	45	62
Advertisement or notice	0	3	18
Other source	1	11	16
General population	0	-	5
Friends, relatives	0	-	1
Formal groups, organizations	1	8	10
Blood samples	0	2	0
Other sources	0	-	-

---

*Percentages may add to more than 100% since respondents could mention more than one subject source.

Table II.5

Which of the following sources are used to obtain subjects for this study?: Type of Research (Percent of Projects)*

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
From among own patients	50%	28%	16%	46%
Referrals by other physicians, professionals	46	16	9	27
Referrals by other subjects	11	7	11	0
Information from records	7	11	12	27
Institutional population via professional access	44	65	52	44
Advertisement or notice	3	7	14	0
Other source	6	10	25	12
General population	-	0	4	0
Friends, relatives	-	0	1	0
Formal groups, organizations	3	10	15	0
Blood samples	1	0	0	12
Other sources	1	-	5	0

---

*Percentages may add to more than 100% since respondents could mention more than one subject source.

Table II.6

Reasons for Selection of Subjects: Type of Institution
(Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Subjects selected because of specific condition	92%	92%	79%
Subjects selected because of absence of specific condition	0	0	0
Selection not related to either the presence or absence of a specific condition	8	8	21
No information	0	-	0
Total	100%	100%	100%

Table II.7

Reasons for Selection of Subjects: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Subjects selected because of specific condition	93%	87%	80%	79%
Subjects selected because of absence of specific condition	0	0	0	0
Selection not related to either presence or absence of a specific condition	7	11	20	21
No information	-	2	0	0
Total	100%	100%	100%	100%

Table II.8

Conditions Used as Basis for Subject Selection: Type of Institution (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Disease or medical condition	85%	89%	38%
Infective and parasitic diseases	0	7	2
Neoplasms	2	11	2
Endocrine, nutritional, metabolic diseases	15	6	1
Diseases of nervous system and sense organs	10	7	5
Diseases of the circulatory system	0	3	0
Diseases of the respiratory system	10	4	0
Diseases of the digestive system	2	7	0
Diseases of the genitourinary system	2	3	0
Complications of pregnancy, childbirth	0	2	0
Diseases of the skin and subcutaneous tissue	2	2	1
Diseases of the musculoskeletal system and connective tissue	4	3	2
Congenital anomalies	8	2	2
Symptoms and ill-defined conditions	1	3	0
Diseases of the blood and blood forming organs	0	6	-
Certain causes of perinatal morbidity and mortality	9	7	2
Nature of injuries	5	1	0
Mental disorders	8	5	19
Medical characteristics	7	10	2
Behavioral problem	1	1	11
Educational problem	1	1	3
Legal problem	0	0	1
Personal adjustment problem	0	0	6
Other behavioral problem	0	0	1

(continued)

Table II.9

Conditions Used as Basis for Subject Selection: Type of Research
(Percent of Projects)*

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Disease or medical condition	96%	60%	38%	80%
Infective and parasitic diseases	5	8	2	3
Neoplasms	10	5	2	18
Endocrine, nutritional, metabolic diseases	11	0	0	0
Disease of nervous system and sense organs	10	10	1	3
Disease of the circulatory system	3	0	0	0
Diseases of the respiratory system	7	0	0	6
Diseases of the digestive system	8	-	0	0
Diseases of the genitourinary system	4	0	0	0
Complications of pregnancy, childbirth	1	2	0	9
Diseases of the skin and subcutaneous tissue	3	0	0	0
Diseases of the musculoskeletal system and connective tissue	5	1	-	0
Congential anomalies	3	5	2	0
Symptoms and ill-defined conditions	2	2	-	0
Diseases of the blood and blood forming organs	5	0	2	0
Certain causes of perinatal morbidity and mortality	9	0	2	0
Nature of injuries	2	0	0	0
Mental disorders	3	26	16	15
Medical characteristics	5	1	11	26

(continued)

Table 9 (continued)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Behavioral problem	-	12%	8%	0%
Educational problem	-	4	2	0
Legal problem	0%	0	1	0
Personal adjustment problem	0	8	4	0
Other behavioral problem	0	0	1	0
Demographic characteristic	14	23	68	3
Age	8	5	16	0
Sex	-	4	3	3
Race	-	1	6	0
Genetic or kinship ties	1	0	1	0
Height/weight	0	0	0	0
Income	2	0	3	0
Social class	0	1	3	0
Educational situation	0	4	19	0
Life/family situation	1	2	9	0
Personal characteristic	2	6	5	0
Geographic location	0	0	2	0
Match on demographic characteristics	0	0	0	0
Other demographic characteristic	0	0	1	0
Other selection criterion	0	10	3	0

---

[*] Percentages may add to more than 100% since respondents could mention more than one condition.

Table III.1

Distribution of Projects by Purpose of Research
(Percent of Projects)

	N	Percent
Benefit subject	119	24%
Benefit others	123	26
Other purpose (subjects selected by condition)*	115	23
Other purpose (subjects not selected by condition)*	41	9
No information	73	18
Total	471	100%

---

*Based upon positive responses to the item: "Are subjects selected because they have a specific disease, condition, problem, or characteristic?"

Table III.2

Distribution of Projects: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=220)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Benefit subjects	35%	46%	11%	17%
Benefit others	30	24	29	21
Other purpose (subjects selected by condition)	19	10	37	47
Other purpose (subjects not selected by condition)	4	10	17	15
No information	12	10	6	0
Total	100%	100%	100%	100%

Table III.3

Primary Intervention or Procedure of Study: Purpose of Research
(Percent of Projects)

	N*	Benefit Subjects	Benefit Others	Other Purpose (Subjects Selected by Condition)	Other Purpose (Subjects not Selected by Condition)	No Information	Total
Biomedical							
Clinical evaluation of bodily tissues or fluids	100	18%	43	24	6	9	100%
Administration of drug, chemical agent or blood	74	53%	21	11	2	13	100%
Administration of vaccines, blood products	8	47%	0	21	0	32	100%
Perinatal care	2	0%	50	50	0	0	100%
Surgical (includes oral)	4	100%	0	0	0	0	100%
Exchange of bodily fluids	1	100%	0	0	0	0	100%
Use of diagnostic and/or therapeutic devices	23	41%	26	11	4	18	100%
Dental care	4	12%	12	76	0	0	100%
Other	4	0%	60	14	26	0	100%
Behavioral intervention							
Educational intervention	21	50%	23	23	0	4	100%
Modification of an organization or a service delivery system	7	72%	18	0	0	10	100%
Behavioral modification and experimentation	11	30%	37	3	30	0	100%
Social psychological therapy	4	50%	0	0	0	50	100%
Other	2	0%	50	50	0	0	100%

Table 3 (continued)

	N*	Benefit Subjects	Benefit Others	Other Purpose (Subjects Selected by Condition)	Other Purpose (Subjects not Selected by Condition)	No Information	Total
Behavioral (other)							
Interviews-questionnaires	30	2%	46	31	19	2	100%
Psychological or educational testing	55	10%	41	39	5	5	100%
Behavioral observation	54	9%	12	40	29	10	100%
Interviews with patient (e.g., medical histories)	8	68%	16	16	0	0	100%
Secondary analysis							
New analysis of existing data	2	0%	28	72	0	0	100%
Review of medical records	3	47%	0	53	0	0	100%
Third party study of tissue of fluids obtained for other purposes	9	17%	23	38	22	0	100%
No information	45	0%	0	0	0	100	100%

---

[*] N's are unweighted; percentages are weighted.

Table III.4

Probability of Risks and Benefits to Subjects: Presearch Primarily Intended to Benefit Subjects*

(Percent of Projects)

(N=119)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	3%	2	9	18	41	6	21	100%
Psychological benefits	4%	5	2	16	23	7	43	100%
Other benefits		-	1%	10	17	6	66	100%
- - - - - - - - - - -								
Minor psychological stress	30%	37	11	3	4	0	15	100%
Serious psychological stress	60%	13	3	0	0	1	23	100%
Minor medical complications	27%	30	20	3	3	1	16	100%
Serious medical complications	49%	19	7	2	2	2	19	100%
Fatal complications	56%	17	6	1	0	1	19	100%
Embarrassment (breach of confidentiality)	60%	19	1	0	0	0	20	100%
Legal risk (breach of confidentiality)	72%	5	1	0	0	0	22	100%
Other risks		2%	3	3	0	-	92	100%

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*Based on data provided by the investigators.

Table III.5

Probability of Risks and Benefits to Subjects: Research Primarily Intended to Benefit Others*

(Percent of Projects)

(N=123)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	9%	8	8	24	8	6	37	100%
Psychological benefits	11%	16	3	10	12	4	44	100%
Other benefits		2%	1	4	10	2	81	100%
Minor psychological stress	20%	47	12	7	1	-	13	100%
Serious psychological stress	64%	18	0	0	0	0	18	100%
Minor medical complications	37%	38	-	-	0	0	25	100%
Serious medical complications	58%	13	0	0	0	0	29	100%
Fatal complications	65%	4	0	0	0	0	31	100%
Embarrassment (breach of confidentiality)	56%	24	7	0	0	0	13	100%
Legal risks (breach of confidentiality)	72%	12	0	0	0	0	16	100%
Other risks		3%	-	2	1	0	94	100%

---

*Based on data provided by the investigators.

Table III.6

Probability of Risks and Benefits to Subjects: Research Conducted for Other Purposes (Subjects Selected by Condition)*
(Percent of Projects)
(N=115)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	11%	4	5	8	7	8	57	100%
Psychological benefits	11%	4	2	12	6	8	57	100%
Other benefits		0%	1	4	16	5	74	100%
- - - - - - - - - - -								
Minor psychological stress	32%	31	11	5	-	2	19	100%
Serious psychological stress	65%	9	4	0	0	0	22	100%
Minor medical complications	32%	22	1	1	0	0	44	100%
Serious medical complications	50%	8	0	0	0	0	42	100%
Fatal complications	55%	3	0	0	0	0	42	100%
Embarrassment (breach of confidentiality)	57%	26	3	1	0	0	13	100%
Legal risks (breach of confidentiality)	69%	8	6	0	0	0	17	100%
Other risks		2%	0	1	0	0	97	100%

---

*Based on data provided by the investigators.

Table III.7

Probability of Risks and Benefits to Subjects: Research Conducted for Other Purposes (Subjects not Selected by Condition)*

(Percent of Projects)

(N=41)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	19%	10	2	0	0	2	67	100%
Psychological benefits	24%	6	5	22	0	0	43	100%
Other benefits		0%	0	11	10	1	78	100%
- - - - - - - - - - -								
Minor psychological stress	35%	32	14	7	1	0	11	100%
Serious psychological stress	76%	13	0	0	0	0	11	100%
Minor medical complications	40%	28	0	0	0	0	32	100%
Serious medical complications	57%	12	0	0	0	0	31	100%
Fatal complications	61%	8	0	0	0	0	31	100%
Embarrassment (breach of confidentiality)	59%	28	1	0	0	0	12	100%
Legal risks (breach of confidentiality)	66%	11	0	0	0	0	23	100%
Other risks		1%	2	0	1	0	96	100%

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*Based on data provided by the investigators.

Table III.8

Probability of Risks and Benefits to Subjects: Biomedical Research*
(Percent of Projects)

(N=220)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	6%	5	8	21	26	7	27	100%
Psychological benefits	12%	8	2	8	6	5	59	100%
Other benefits		1%	1	5	10	2	81	100%
- - - - - - - - - -								
Minor psychological stress	21%	38	11	3	2	-	25	100%
Serious psychological stress	54%	14	1	0	0	-	31	100%
Minor medical complications	22%	45	11	2	1	-	19	100%
Serious medical complications	54%	20	3	1	1	1	20	100%
Fatal complications	64%	12	3	-	0	-	21	100%
Embarrassment (breach of confidentiality)	60%	9	2	0	0	0	29	100%
Legal risk (breach of confidentiality)	65%	4	1	0	0	0	30	100%
Other risks		3%	2	1	-	-	94	100%

---

*Based on data provided by the investigators.

Table III.9

Probability of Risks and Benefits to Subjects: Other Behavioral Research*

(Percent of Projects)

(N=147)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	9%	6	2	6	2	2	73	100%
Psychological benefits	6%	9	3	19	13	5	45	100%
Other benefits		-	1%	5	16	2	76	100%
Minor psychological stress	28%	32	11	10	-	2	17	100%
Serious psychological stress	66%	11	2	0	0	0	21	100%
Minor medical complications	34%	9	0	0	0	0	57	100%
Serious medical complications	41%	2	0	0	0	0	57	100%
Fatal complications	41%	2	0	0	0	0	57	100%
Embarrassment (breach of confidentiality)	43%	38	4	-	0	0	15	100%
Legal risk (breach of confidentiality)	62%	13	2	0	0	0	23	100%
Other risks		1%	-	1	-	0	98	100%

---

*Based on data provided by the investigators.

Table III.10

Probability of Risks and Benefits to Subjects: Behavioral Intervention Research*
(Percent of Projects)
(N= 45)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	16%	1	8	7	13	7	48	100%
Psychological benefits	12%	3	0	9	37	12	27	100%
Other benefits		0%	1	12	26	14	47	100%
- - - - - - - - - - -								
Minor psychological stress	32%	40	10	1	2	1	14	100%
Serious psychological stress	61%	12	5	0	0	0	22	100%
Minor medical complications	50%	3	2	0	0	0	45	100%
Serious medical complications	52%	4	0	0	0	0	44	100%
Fatal complications	52%	4	0	0	0	0	44	100%
Embarrassment (breach of confidentiality)	52%	25	5	1	0	0	17	100%
Legal risk (breach of confidentiality)	71%	5	1	0	0	0	23	100%
Other risks		0%	2	11	0	0	87	100%

---

*Based on data provided by the investigators.

Table III.11

Probability of Risks and Benefits to Subjects: Secondary Analysis Research*
(Percent of Projects)

(N=14)

	None	Very Low	Low	Medium	High	Unknown	Not Applicable	Total
Medical benefits	7%	0	11	0	6	6	70	100%
Psychological benefits	7%	0	0	0	0	0	93	100%
Other benefits		0%	0	0	6	9	85	100%
Minor psychological stress	46%	6	0	0	0	0	48	100%
Serious psychological stress	46%	6	0	0	0	0	48	100%
Minor medical complications	53%	11	0	0	0	0	36	100%
Serious medical complications	53%	11	0	0	0	0	36	100%
Fatal complications	58%	6	0	0	0	0	36	100%
Embarrassment (breach of confidentiality)	49%	15	15	0	0	0	21	100%
Legal risk (breach of confidentiality)	58%	9	15	0	0	0	18	100%
Other risks		0%	0	0	0	0	100	100%

---

*Based on data provided by the investigators.

Table III.12

From what you have learned in this study, which of the following best describes your present assessment of benefits to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Much more benefit than expected	12%	1%	1%	1%
Somewhat more benefits than expected	9	14	9	0
Benefits as expected	46	45	50	52
Somewhat less benefit than expected	8	3	2	10
Much less benefit than expected	3	2	0	0
Assessment cannot be made	20	21	26	11
No information	2	14	12	26
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators

Table III.13

From what you have learned in this study which of the following best describe your present assessment of risks to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Much more risk than expected	3%	0%	0%	0%
Somewhat more risk than expected	1	2	1	0
Risk as expected	58	67	58	69
Somewhat less risk than expected	7	6	6	0
Much less risk than expected	7	4	3	0
Unable to assess	13	11	14	4
No information	11	10	18	27
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.14

Before involving subjects in this study,
how certain were you that you knew all of the risks to subjects?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Very certain	51%	55%	71%	83%
Fairly certain	41	40	26	17
Not very certain	4	-	0	0
Not at all certain	-	0	0	0
No information	4	5	3	0
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.15

From what you have learned in this study, which of the following best describes your present assessment of benefits to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Type of Research			
	Biomedical (N=220)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Much more benefit than expected	5%	3%	2%	0%
Somewhat more benefits than expected	9	11	9	0
Benefits as expected	38	32	56	9
Somewhat less benefit than expected	4	12	2	0
Much less benefit than expected	2	0	-	0
Assessment cannot be made	22	29	16	55
No information	20	7	15	36
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.16

From what you have learned in this study which of the following best describe your present assessment of risks to subjects as compared to your expectations when the research began?*
(Percent of Projects)

	Type of Research			
	Biomedical (N= 220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N= 147)	Secondary Analysis (N= 14)
Much more risk than expected	1%	0%	0%	0%
Somewhat more risk than expected	1	5	0	0
Risk as expected	56	43	64	27
Somewhat less risk than expected	6	4	6	0
Much less risk than expected	4	10	2	0
Unable to assess	13	22	8	32
No information	19	16	20	41
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.17

Before involving subjects in this study, how certain were you that you knew all of the risks to subjects?*
(Percent of Projects)

	Type of Research			
	Biomedical (N= 220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N= 147)	Secondary Analysis (N= 14)
Very certain	56%	40%	59%	53%
Fairly certain	28	44	31	26
Not very certain	2	3	0	0
Not at all certain	-	0	0	0
No information	14	13	10	21
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.18

Before you began involving subjects in this study, which one of the following statements best describe your assessment of the balance of risk and benefits to the average subject?*
(aside from any financial benefit)
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Much more risk than benefit	0%	1%	0%	0%
Somewhat more risk than benefit	0	-	1	2
Equal risk and benefit	3	5	2	1
Somewhat more benefit than risk	2	9	13	9
Much more benefit than risk	82	43	29	28
No risk or benefit	4	34	43	55
Assessment cannot be made	3	2	3	1
No information	6	6	9	4
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.19

How would you assess the balance of risks and benefits to subjects at the present time?*
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Much more risk than benefit	0%	-%	0%	0%
Somewhat more risk than benefit	2	0	3	2
Equal risk and benefit	3	3	3	1
Somewhat more benefit than risk	6	13	14	10
Much more benefit than risk	75	42	30	28
No risk or benefit	4	30	38	53
Assessment cannot be made	5	4	3	1
No information	5	8	9	5
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.20

Before you began involving subjects in this study,
which one of the following statements best describe your assessment
of the balance of risk and benefits to the average subject?*
(aside from any financial benefit)
(Percent of Projects)

	Type of Research			
	Biomedical (N=220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N=147)	Secondary Analysis (N= 14)
Much more risk than benefit	-%	0%	-%	0%
Somewhat more risk than benefit	1	0	-	0
Equal risk and benefit	4	1	3	3
Somewhat more benefit than risk	8	3	8	0
Much more benefit than risk	47	72	36	6
No risk or benefit	20	2	41	69
Assessment cannot be made	3	16	3	0
No information	17	6	9	22
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table III.21

How would you assess the balance of risks and benefits to subjects at the present time?*
(Percent of Projects)

	Type of Research			
	Biomedical (N= 220)	Behavioral Intervention (N= 45)	Behavioral (Other) (N=147)	Secondary Analysis (N= 14)
Much more risk than benefit	0%	0%	-	0%
Somewhat more risk than benefit	2	0	0	15
Equal risk and benefit	3	1	3	3
Somewhat more benefit than risk	9	8	12	0
Much more benefit than risk	48	66	32	6
No risk or benefit	17	1	39	55
Assessment cannot be made	4	18	4	0
No information	17	6	10	21
Total	100%	100%	100%	100%

---

*Based on data provided by the investigators.

Table IV.1

Modifications by Review Committee Regarding Informed Consent: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Did the review committee require that you make modifications in your study in regard to how consent would be obtained from subjects?			
Yes, change required*	35%	23%	23%
Required written (rather than oral) consent	1	4	5
Required addition of material to be disclosed	22	8	7
Required simplification of material to be disclosed	2	3	3
Required alterations in material to be disclosed	10	7	2
Required change in setting in which consent obtained	0	0	0
Required change in timing of obtaining consent	0	0	0
Required change in who obtains consent	0	-	0
Required presence of witnesses when consent obtained	0	1	0
Required proxy consent	0	-	0
Required subject as well as proxy consent	0	-	2
Other changes	1	1	4
No, no change required	58	76	75
No information	7	1	2
Total	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.2

Modifications by Review Committee Regarding Informed Consent: Type of Research (Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Did the review committee require that you make modifications in your study in regard to how consent would be obtained from subjects?				
Yes, change required*	27%	12%	23%	41%
Required written (rather than oral) consent	0	7	4	27
Required addition of material to be disclosed	11	4	8	7
Required simplification of material to be disclosed	3	0	2	0
Required other changes in material to be disclosed	10	1	2	0
Required change in setting in which consent obtained	0	0	0	0
Required change in timing of obtaining consent	0	0	2	0
Required change in who obtains consent	-	0	0	0
Required presence of witnesses when consent obtained	0	0	1	0
Required proxy consent	-	0	0	0
Required subject as well as proxy consent	2	0	0	0
Other changes	1	0	4	7
No, no change required	71	88	75	59
No information	2	0	2	0
Total	100%	100%	100%	100%

---

* Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.3

Type of Consent Obtained: Type of Institution
(Percent of Projects)

	Type of Institution		
In this study, is either oral or written consent obtained from subjects or someone acting for subjects?	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Yes, oral	8%	10%	14%
Yes, written	64	47	52
Yes, both	28	31	26
No consent obtained/needed*	0	12	8
Return of questionnaire implies consent	0	1	1
Have sign-up sheet	0	0	0
Participation voluntary--no further specification	0	0	1
Anonymous/confidential research	0	1	0
Research involves necessary treatment/procedure	0	0	0
Subject's own physician determines participation	0	0	0
Research involves routine treatment/procedures	0	5	3
Only existing records used	0	1	0
Materials from previous research being used	0	3	0
Consent obtained elsewhere	0	-	0
Participation requested/recommended by someone other than research staff	0	0	0
Not required by review committee	0	2	2
Investigator says "no risk/harm involved for subjects"	0	1	2
Other	0	-	1
No information	0	0	0
Total	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "no" response was checked. More than one of the offset responses could be checked in any project.

Table IV.4

Frequency of Consent Obtained: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
In this study, is either oral or written consent obtained from subjects or someone acting for subjects?	-			
Yes, oral	7%	10%	18%	0%
Yes, written	52	49	54	13
Yes, both	36	33	20	6
No consent obtained/needed*	5	8	8	81
Return of questionnaire implies consent	-	4	1	0
Have sign-up sheet	0	0	0	0
Participation voluntary--no further specification	0	0	1	0
Anonymous/confidential research	0	0	0	10
Research involves necessary treatment/procedure	0	0	0	0
Subject's own physician determines participation	0	0	0	0
Research involves routine procedures/treatment	5	0	3	0
Only existing records used	-	0	0	17
Materials from previous research being used	0	0	0	49
Consent obtained elsewhere	0	0	0	3
Participation requested/recommended by someone other than research staff	0	0	0	0
Not required by review committee	0	0	2	27
Investigator says "no risk/harm involved for subjects"	0	0	2	6
Other	0	5	0	0
No information	0	0	0	0
Total	100%	100%	100%	100%

*Percentages in the offset columns represent distributions among those projects where the "no" response was checked. More than one of the offset responses could be checked in any project.

Table IV.5

Oral Explanation of Study: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Are subjects (or proxies) given an oral explanation of the study?			
Yes	93%	82%	77%
No	0	3	11
Question inappropriate	0	12	8
No information	7	3	4
Total	100%	100%	100%

Table IV.6

Oral Explanation of Study: Type of Research
(Percent of Projects)

	Type of Research			
Are subjects (or proxies) given an oral explanation of the study?	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Yes	88%	77%	81%	19%
No	2	7	10	0
Question inappropriate	5	8	8	81
No information	5	8	1	0
Total	100%	100%	100%	100%

Table IV.7

Who Obtains Consent: Type of Institution
(Percent of Projects)

	Type of Institution		
Who obtains consent?	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Investigator usually obtains consent	32%	33%	48%
Investigator shares consent responsibility	55	32	27
Others usually obtain consent	13	23	17
Question inappropriate	0	1	8
No information	0	11	0
Total	100%	100%	100%

Table IV.8

Who Obtains Consent: Type of Research
(Percent of Projects)

	Type of Research			
Who obtains consent?	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Investigator usually obtains consent	35%	36%	44%	13%
Investigator shares consent responsibility	38	31	31	6
Others usually obtain consent	21	25	17	0
Question inappropriate	5	8	8	81
No information	1	0	0	0
Total	100%	100%	100%	100%

– Table IV.9

Others Who Obtain Consent: Type of Institution (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Study Staff			
Professional colleague	36%	25%	18%
Resident or research fellow in medicine	20	13	2
Intern/medical student/dental student	0	1	-
Graduate student	2	4	11
Nurse/physical therapist	19	8	0
Technician/dental assistant/physician's assistant	5	2	-
Research assistant/students	12	7	22
Interviewer	0	1	5
Other	5	5	5
Social worker/counselor	5	1	2
Secretary/receptionist	0	1	0
Elementary/secondary school staff	0	2	-
Other	0	1	3
Staff (not on study)			
Professional colleague	10	6	1
Resident or research fellow in medicine	2	4	0
Intern/medical student/dental student	5	-	0
Graduate student	0	-	0
Nurse/physical therapist	12	1	0
Technician/dental assistant/physician's assistant	0	0	0
Research assistant/students	0	0	0
Interviewer	0	-	-
Other	5	2	11
Social worker/counselor	0	0	3
Secretary/receptionist	0	0	2
Elementary/secondary school staff	0	2	2
Other	5	0	4
Question inappropriate	36	47	49
No information	5	2	0

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*Percentages may add to more than 100% since more than one response could be checked.

Table IV.10

Who Else is Present When Consent Obtained: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Aside from yourself and the subject (and/or proxy), is anyone else usually present when consent is sought?			
Yes*	60%	55%	46%
Family member	26	28	14
Physician or dentist	17	15	3
Nurse	51	25	3
Research assistant	22	17	22
Other	6	9	19
No	22	22	32
Question inappropriate	2	14	14
No information	16	9	8
Total	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.11

Who Else is Present When Consent Obtained: Type of Research (Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Aside from yourself and the subject (and/or the proxy), is anyone else usually present when consent is sought?				
Yes*	58%	52%	49%	13%
Family member	27	15	22	6
Physician or dentist	18	8	3	6
Nurse	37	10	3	12
Research assistant	22	29	17	0
Other	9	21	15	6
No	24	22	31	0
Question inappropriate	9	13	10	81
No information	9	13	10	6
Total	100%	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.12

Emphasis in Description of Study: Purpose of Research (Percent of Projects)*

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
e any of the following emphasized en you described this study to a ospective subject or proxy?				
rect benefit to subject	80%	39%	37%	19%
nefit to other individuals in the ture	58	70	48	28
nefit to scientific knowledge	49	46	50	34
mething else	6	9	9	12
No direct benefit to subject	0	2	2	0
Emphasized risks, hazards	2	5	2	2
Other (unspecified)	4	2	5	10
estion inappropriate	15	18	24	30
information	1	6	4	3

---

ercentages may add to more than 100% since more than one response could be hecked.

Table IV.13

Major Emphasis in Description of Study: Purpose of Research (Percent of Projects)

	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Where more than one issue is emphasized in describing this study, which one is emphasized most?				
Direct benefit to the subject	37%	10%	10%	0%
Benefit to other individuals in the future	10	27	18	2
Benefit to scientific knowledge	1	4	10	16
No direct benefit to subject	0	0	0	0
Something else	1	1	0	1
Question inappropriate	35	47	51	74
No information	16	11	11	7
Total	100%	100%	100%	100%

Table IV.14

Participation Request or Recommendation: Purpose of Research (Percent of Projects)

When you are obtaining consent, is participation in this study presented to subjects (or proxies) as your request, your recommendation, or both?	Purpose of Research Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Request	27%	65%	55%	61%
Recommendation	19	2	4	2
Both	27	8	8	0
Neither	10	3	5	5
Question inappropriate	14	17	24	30
No information	3	5	4	2
Total	100%	100%	100%	100%

Table IV.15

Information Not Divulged to Subjects: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
In some research the design of the study requires that certain information not be divulged to subjects. Is that the case in this study?			
Yes, certain information not divulged*	12%	13%	36%
Existence of study	0	2	0
Purpose of study	0	5	20
Purpose of specific procedures	5	6	18
Existence of confederate	0	0	-
Tape recording/filming/photographing	0	1	0
Possible benefits to subjects	5	1	4
Possible risks or discomforts to subjects	0	0	1
Medication or treatment being used	2	2	6
Other	5	5	8
No, not required by study design or all information divulged	88	86	64
No information	0	1	-
Total	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.16

Information Not Divulged to Subjects: Type of Research (Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
In some research the design of the study requires that certain information not be divulged to subjects. Is that the case in this study?				
Yes, certain information not divulged*	8%	21%	41%	0%
Existence of study	1	2	-	0
Purpose of study	-	10	24	0
Purpose of specific procedures	1	9	24	0
Existence of confederate	0	0	-	0
Tape recording/filming/photographing	0	0	1	0
Possible benefits to subjects	0	0	7	0
Possible risks or discomforts to subjects	0	0	1	0
Medication or treatment being used	4	2	4	0
Other	2	2	13	0
No, not required by study design or all information divulged	92	78	58	97
No information	-	1	1	3
Total	100%	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.17

Subjects Told Things Not True: Type of Institution
(Percent of Projects)

For purposes of your study is it necessary to tell some subjects some things which are not true?	Type of Institution Children's Hospitals (N=44)	 Other Biomedical (N=231)	 Other (N=150)
Yes, necessary to tell things not true*	0%	1%	7%
Existence of study	0	0	0
Purpose of study	0	0	3
Purpose of specific procedures	0	0	3
Existence of confederate	0	0	-
Tape recording/filming/photographing	0	0	0
Possible benefits to subjects	0	0	0
Possible risks or discomforts to subjects	0	-	0
Medication or treatment being used	0	0	2
Other	0	1	1
No, not necessary	99	99	93
No information	1	-	-
Total	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.18

Subjects Told Things Not True: Type of Research (Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
For purposes of your study is it necessary to tell some subjects some things which are not true?				
Yes, necessary to tell things not true*	0%	0%	7%	0%
Existence of study	0	0	0	0
Purpose of study	0	0	3	0
Purpose of specific procedures	0	0	3	0
Existence of confederate	0	0	-	0
Tape recording/filming/ photographing	0	0	0	0
Possible benefits to subjects	0	0	0	0
Possible risks or discomforts to subjects	0	0	0	0
Medication or treatment being used	0	0	2	0
Other	0	0	1	0
No, not necessary	100	99	93	97
No information	-	1	0	3
Total	100%	100%	100%	100%

---

*Percentages in the offset columns represent distributions among those projects where the "yes" response was checked. More than one of the offset responses could be checked in any project.

Table IV.19

Payment for Participation: Purpose of Research
(Percent of Projects)

	Purpose of Research			
Are subjects paid? If so, what is the average payment?	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects n Selected by Condition) (N=41)
All subjects paid	1%	8%	3%	10%
Some subjects paid	0	8	8	10
Average payment				
$1-5	--	5	6	15
$6-10	0	2	3	0
$11-15	0	0	1	0
$16-20	0	1	0	0
$21-25	0	4	0	1
$26-50	0	4	0	0
$51-75	0	0	0	0
$76-100	0	0	1	0
$101-150	0	0	0	2
$151-200	0	0	0	2
$201-300	0	0	0	0
More than $300	0	0	0	0
Other payment (e.g., dollars per hour)	1	0	0	0
No subjects paid	97	83	86	76
No information	2	1	3	4
Total	100%	100%	100%	100%

Table IV.20

Difficulty in Deciding to Participate: Purpose of Research
(Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
w difficult for prospective bjects is the decision to rticipate?				
ry difficult	1%	2%	1%	0%
mewhat difficult	12	12	0	2
t very difficult	26	28	22	32
t at all difficult	47	36	55	34
estion inappropriate	9	12	16	22
information	5	10	6	10
Total	100%	100%	100%	100%

Table IV.21

People Decline to Participate: Purpose of Research (Percent of Projects)

	Purpose of Research			
	Benefit Subjects (N=119)	Benefit Others (N=123)	Other Purpose (Subjects Selected by Condition) (N=115)	Other Purpose (Subjects not Selected by Condition) (N=41)
Have any people declined to participate in this study after having been given information about it?				
Yes, some declined	36%	43%	36%	50%
percentage declining	7	13	10	11
No, none declined	50	38	41	24
Question inappropriate	9	12	16	22
No information	5	7	7	4
Total	100%	100%	100%	100%

Table IV.22

Instances of Proxy Consent: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Are there instances in this study in which proxy consent is involved?			
Yes	94%	69%	67%
No	1	16	22
Question inappropriate	0	12	8
No information	5	3	3
Total	100%	100%	100%

Table IV.23

Instances of Proxy Consent: Type of Research
(Percent of Projects)

	Type of Research			
	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Are there instances in this study in which proxy consent is involved?				
Yes	79%	64%	69%	13%
No	11	20	22	6
Question inappropriate	5	8	8	81
No information	5	8	1	0
Total	100%	100%	100%	100%

Table IV.24

Circumstances under Which Proxy Consent Used: Type of Institution (Percent of Projects)*

Under what circumstances has proxy consent been obtained?	Type of Institution Children's Hospitals (N=44)	 Other Biomedical (N=231)	 Other (N=150)
Age	90%	64%	58%
Intellect	10	6	9
Degree of illness	1	4	3
Other	0	1	3
Question inappropriate	3	30	33
No information	7	4	4

---

*Percentages may add to more than 100% since more than one response could be checked.

Table IV.25

Circumstances under Which Proxy Consent Used: Type of Research (Percent of Projects)*

Under what circumstances has proxy consent been obtained?	Type of Research Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Age	74%	52%	62%	12%
Intellect	10	9	4	0
Degree of illness	5	0	2	0
Other	-	3	2	0
Question inappropriate	19	33	32	88
No information	5	10	2	0

---

[*] Percentages may add to more than 100% since more than one response could be checked.

Table IV.26

Who Acts as Proxy: Type of Institution (Percent of Projects)*

Who is asked to give proxy consent or subjects in your study?	Type of Institution Children's Hospitals (N=44)	 Other Biomedical (N=231)	 Other (N=150)
Parent or other relatives	88%	66%	58%
Legal guardian	40	18	25
Subjects own physician	2	2	0
Institutional representative	5	-	3
Courts	0	1	6
Someone else	0	0	-
Question inappropriate	3	30	33
No information	9	4	3

---

*Percentages may add to more than 100% since more than one response could be checked.

Table IV.27

Who Acts as Proxy: Type of Research (Percent of Projects)*

Who is asked to give proxy consent or subjects in your study?	Type of Research Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Parent or other relatives	75%	52%	63%	12%
Legal guardian	23	33	23	6
Subjects own physician	2	0	0	0
Institutional representative	2	1	2	0
Courts	-	4	5	6
Someone else	0	1	0	0
Question inappropriate	19	32	31	88
No information	5	13	1	0

---

*Percentages may add to more than 100% since more than one response could be checked.

Table IV.28

Subjects Reluctant to Participate: Type of Institution (Percent of Projects)

	Type of Institution		
In this study, how often do instances arise in which subjects for whom proxy consent has been obtained are reluctant to participate?	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Often	10%	2%	0%
Sometimes	11	4	5
Rarely	12	10	14
Never	51	45	39
Question inappropriate	3	30	33
No information	13	9	9
Total	100%	100%	100%

Table IV.29

Subjects Reluctant to Participate: Type of Research (Percent of Projects)

	Type of Research			
In this study, how often do instances arise in chich subjects for whom proxy consent has been obtained are reluctant to participate?	Biomedical (N=219)	Behavioral Intervention (N=45)	Behavioral (Other) (N=147)	Secondary Analysis (N=14)
Often	4%	0%	1%	0%
Sometimes	7	8	2	0
Rarely	11	13	14	0
Never	50	29	43	12
Question inappropriate	19	32	31	88
No information	9	18	9	0
Total	100%	100%	100%	100%

Table IV.30

Proxy Consent Protection for Subject: Type of Institution (Percent of Projects)

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
Recognizing that it is necessary to use proxy consent in some circumstances, from your general experience, do you feel that proxy consent protects the interests of subjects very well, fairly well, not very well, or not at all?			
Very well	58%	51%	35%
Fairly well	24	18	25
Not very well	1	5	12
Not at all	2	2	2
Question inappropriate	0	12	8
No information	15	12	18
Total	100%	100%	100%

Table IV.31

Proxy Consent Inadequate Protection: Type of Institution (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N=44)	Other Biomedical (N=231)	Other (N=150)
In what ways or in what situations may proxy consent not adequately protect subjects?			
Subjects do not know they are involved in research	0%	-	0%
Subjects are not given complete information	3	1%	4
Subjects not told about risks/hazards	0	0	0
Subjects have no choice about participating	10	4	10
Subject's right to privacy is violated	0	-	0
Subjects are incapable of giving consent	1	1	-
When children are involved	0	-	0
Proxy not adequately informed about research	2	4	4
Proxy not adequately informed about risks/hazards	2	1	1
Proxy may not care about/want to protect subject	2	4	6
When proxy incapable of understanding research	7	4	7
When proxy is a representative of the institution in which the research in done	0	0	2
When proxy feels under obligation to the institution	0	0	0
When proxy does not want to assume responsibility for subject	0	0	0
When proxy believes some good could come from subject's condition	0	0	0
When proxy has something to gain from subject's participation	1	0	1
Other conflicts of interest of proxy	0	1	0
When research dangerous/potentially harmful	2	0	2
Oppose proxy consent in general	0	0	0
Think consent, in general, no guarantee	0	-	0
Other	2	1	1
Question inappropriate	68	73	59
No information	10	10	6

*Percentages may add to more than 100% since more than one response could be checked.

Table V.1

Types of Consent Forms Used: Types of Institutions (Percent of Projects)

Type of Form	Type of Institution Children's Hospitals (N=35)	 Other Biomedical (N=158)	 Other (N=94)
Institutional standard form with no details included about the particular study	18%	8%	12%
Institutional standard form which included details about the particular study	2	15	9
Original form	77	68	77
Type of form not determined	3	9	2
No information	0	0	--
Total	100%	100%	100%

---

*Table based on projects for which we have consent forms.

Table V.2

Distribution of Long and Short Consent Forms: Type of Institution*
(Percent of Projects)

	Type of Institution		
Length of Form	Children's Hospitals (N= 35)	Other Biomedical (N=158)	Other (N= 94)
Short (less than 300 words)	63%	77%	77%
Long (more than 300 words)	37	23	23
No information	0	0	0
Total	100%	100%	100%

---

*Table based on projects for which we have consent forms.

Table V.3

Are subjects given a copy of the consent form to keep?: Type of Institution*
(Percent of Projects)

	Type of Institution		
	Children's Hospitals (N= 35)	Other Biomedical (N=158)	Other (N= 94)
Yes	12%	10%	23%
Upon request	14	7	5
No	67	74	65
No information	7	9	7
Total	100%	100%	100%

---

*Table based on those projects for which we have consent forms.

Table V.4

Index of Consent Form Completeness: Type of Institution*
(Percent of Projects)

	Type of Institution		
Degree of Completeness **	Children's Hospitals (N=35)	Other Biomedical (N=158)	Other (N=94)
1 Complete or nearly complete	20%	20%	5%
2	17	19	9
3	25	19	34
4	18	19	18
5	17	15	12
6 Totally or nearly incomplete	3	5	16
No information	0	3	6
Total	100%	100%	100%

---

*Table based on projects for which we have consent forms.

**This index is based upon six items: description of (1) purpose of the research, (2) the procedures involved, (3) the risks, (4) the benefits, and the presence of statements indicating that (5) participation is voluntary or that subjects could withdraw without prejudice and that (6) subjects and proxies might ask questions about participation. A consent form in the most complete category, for example, would contain at least four detailed descriptions and two brief mentions of these six elements. A form in the least complete category could include no complete descriptions and no more than one brief mention of any of these elements. Sec the following page for more information about the coding schemes used in the index.

The coding of consent forms for completeness. Four of the six components comprising the consent form completeness index were scored for degree of mention as follows:

0 no mention

1 unspecific certified statement

2 brief mention

3 detailed description

The components concerning two elements ("Questions" and "Withdrawal") were coded somewhat differently, as will be described below.

A certified statement indicates that the subject or proxy acknowledges having been informed regarding an issue such as the purpose of the research or the risks of participation. Certified statements may include reference to specific details of the issue or they may be "unspecific," simply indicating that the subject or proxy has been informed. Unspecific certified statements were coded 1; those with specific information about the issues were coded for the degree of detail presented.

Purpose. The extent to which the form contains a description of the purpose of the study and whether or not it contains an unspecific certified statement of purpose is coded as degree of "Purpose."

Procedures. The content relating to procedures was coded in the same way as that of purpose.

Benefits. "Benefits" is coded on the basis of the extent to which the form contains statements discussing the probability of medical benefit to the subject and statements discussing general benefits to the subject. Statements of the nature of benefits or lack thereof are regarded as detailed descriptions.

Risks. The extent to which the form contains statements regarding severity of risk is coded as "Risk." Also included in this code are statements pertaining to psychological, medical, and minor risks and discomforts and unspecific certified statements of risk. The most detailed discussion among these items defines the code value assigned.

Subject Withdrawal. Coded in "Subject Withdrawal" is the extent to which the form contains statements to the effect that participation is voluntary or that the subject is free to withdraw without prejudice. For this element, a certified statement was assigned a value of 2 (rather than 1) because such a statement implicitly involves a brief description.

Questions. This component was coded either 0 or 3, corresponding to the absence or presence of an invitation to ask questions.

Index of consent form completeness. A summary measure combining the six elements described above was constructed by averaging the six scores. In cases where more than two scores were unascertainable, the index for that consent form received a score of "no information."

Table V.5

Components of Index of Consent Form Completeness: Type of Institution*
(Percent of Projects)

Type of Institution

	Children's Hospitals (N= 35)						Other Biomedical (N= 158)						Other (N= 94)					
Component	No Mention	Unspecific Certified Statement**	Brief Mention	Detailed Description	No information	Total	No Mention	Unspecific Certified Statement**	Brief Mention	Detailed Description	No information	Total	No Mention	Unspecific Certified Statement**	Brief Mention	Detailed Description	No information	Total
Purpose	13%	3	63	21	0	100	25	7	58	9	1	100	29	6	54	11	0	100%
Procedures	9%	7	61	23	0	100	4	11	60	23	1	100	18	4	50	28	0	100%
Benefits	50%	8	8	34	0	100	34	24	15	26	1	100	74	4	12	10	-	100%
Risks***	15%	15	15	49	6	100	35	12	22	27	4	100	70	6	8	11	5	100%
Withdrawal	46%	0	34	20	0	100	23	0	44	32	1	100	14	0	60	24	2	100%
Questions ******	63%	0	0	37	0	100	46	0	0	53	1	100	50	0	0	50	0	100%

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*Table based on projects for which we have consent forms.

**For example, "I certify that I have been informed about the purpose, procedures, and risks of this study."

***Of those projects which made no mention of risk in either the written consent form or the oral consent information statement, more than two thirds were characterized by investigators on our questionnaire as entailing at least a very low probability of minor harm to the subject.

****Coded dichotomously: either provided statement inviting questions or did not.

Table V.6

Degree of consent form mention*: Availability of alternative procedures.
By type of Institution
(Table based on forms from projects described as intending to benefit subjects)
(Percent of forms)

Mention of Alternatives	Type of Institution Children's Hospitals (N=21)	 Other Biomedical (N=88)	 Other (N=27)
No mention	90%	80%	98%
Alternatives exist	7	10	0
Alternatives offered	1	2	0
No alternatives	2	7	0
No information	0	1	2
Total	100%	100%	100%

---

*Of those projects whose forms are indicated above as not mentioning alternatives, an additional 13 percent mentioned alternatives in their oral statement.

Table V. 7

Degree of consent form mention*: Experimental nature of the research. Table based on forms from projects described by investigators as containing "experimental" elements (Percent of forms)

	Type of Institution		
Mention of experimental nature of projects in consent form**	Children's Hospitals (N=14)	Other Biomedical (N=41)	Other (N=6)
No mention	66	61	29
Brief mention	21	31	0
Experimental elements identified	13	8	71
No information	0	0	0
Total	100	100	100

---

*Of those projects above whose forms do not mention experimental nature of the research, an additional 4 percent mentioned the experimental nature in their oral consent information statement.

**Determined by whether the words "experiment," "experimental," "research," "testing," or "investigational drug" appear in the consent form.

Table V.8

Percentage of mention of consent form elements of information not covered by completeness analyses. All consent forms. (N=304 forms)

Element	% Mentioned	% Not Mentioned	No Information	Total
Expected duration of participation	32%	67%	1%	100%
Discussion of confidentiality	39%	61	--	100%
Mention of review committee approval	4%	95	1	100%
Agreement of participation included	90%	9	1	100%
Discuss voluntary nature of participation	38%	62	0	100%
Mention injuries will be treated	1%	98%	1	100%
Mention harm will be compensated	0%	99	1	100%
Investigator or institution released from responsibility for harm incurred	1%	98	1	100%
Project contact information (phone number) included	12%	88	--	100%
Provision to contact subject for future research	1%	98	1	100%
Provision to allow future use of data	12%	87	1	100%
Results will be made available to subject	11%	88	1	100%

Table V.9

Readability of Short Consent Forms: Type of Institution

(N=216)
(Percent of Projects)*

Readability**

	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (*Time*)	Fairly Difficult (*Atlantic*)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects	0%	1	1	13	13	55	17	--	100%
Children's Hospitals	0%	0	1	12	0	60	27	0	100%
Other Biomedical	0%	1	0	9	12	56	22	0	100%
Other Institutions	0%	--	4	19	20	51	6	--	100%

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*Table based on projects for which we have consent forms.

**An explanation of the procedure for coding readability appears after Table V.12

Table V.10

Readability of Long Consent Forms--Description of Purpose: Type of Institution

(N= 71)
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects	0%	0	4	7	7	42	26	14	100%
Children's Hospitals	0%	0	16	2	3	59	18	2	100%
Other Biomedical	0%	0	0	5	11	42	35	7	100%
Other Institutions	0%	0	0	13	6	28	19	34	100%

---

*Table based on projects for which we have consent forms.

Table V.11

Readability of Long Consent Forms--Description of Procedures: Type of Institution

(N= 71)
(Percent of Projects)*

	Readability								
	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects	0%	0	4	23	28	35	10	0	100%
Children's Hospitals	0%	0	2	20	36	26	16	0	100%
Other Biomedical	0%	0	0	23	29	39	9	0	100%
Other Institutions	0%	0	13	24	21	36	6	0	100%

---

*Table based on projects for which we have consent forms.

Consent form readibility. The Flesch Readability Yardstick* is a statistical formula developed for the objective measurement of readability and comprehension difficulty. The "reading ease score" for a selected reading passage is based on word length, i.e., the average number of syllables per 100 words, and sentence length, i.e., the average number of words per sentence. The Flesch formula was selected for the analysis of the consent forms over other readability formulas primarily because of its general applicability to technical material.

For the purposes of this report, consent forms were classified as either "short" or "long" forms. If the particular form in question contained less than 300 words, an overall readability level was determined by analyzing the entire passage. For those forms where the text exceeeded 300 words, readability scores were obtained separately for three aspects of the form: purpose, procedures, and risk/discomfort.

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*Flesch, Rudolf, "A New Readability Yardstick," Journal of Applied Psychology, vol. 32, no. 3, June 1948, pp. 221-233.

Table V.12

Readability of Long Consent Forms--Description of Risk: Type of Institution

(N= 71)
(Percent of Projects)*

Readability

	Very Easy (Comics)	Easy (Pulp fiction)	Fairly Easy (Slick fiction)	Standard (Time)	Fairly Difficult (Atlantic)	Difficult (Scholarly, academic)	Very Difficult (Scientific, professional)	No Information	Total
All Projects	3%	--	0	5	20	30	8	34	100%
Children's Hospitals	0%	2	0	0	49	18	15	16	100%
Other Biomedical	6%	0	0	10	16	46	9	13	100%
Other Institutions	0%	0	0	3	4	17	0	76	100%

---

*Table based on projects for which we have consent forms.

Table VI . 1

Attitudes of Investigators Toward Review Procedure and Committees: Children's Hospitals*

	To a Large Extent	To Some Extent	Not at All	Total
Procedure protected rights of subject (N=31)	70%	29	1	100%
Procedure improved quality of research (N=31)	38%	53	9	100%
Precedure an unwarranted intrusion on investigator's autonomy (N=31)	0%	10	90	100%
Procedure runs with reasonable effeciency (N=31)	52%	48	0	100%
Committee gets into areas not appropriate to its function (N=30)	1%	61	38	100%
Committee makes judgments it is not qualified to make (N=31)	1%	49	50	100%
Procedure impeded progress of research (N=30)	0%	14	86	100%

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*Percentages do not include non-respondents.

Table VI . 2

Attitudes of Investigators Toward Review Procedure and Committees: Other Biomedical Institutions*

	To a Large Extent	To Some Extent	Not at All	Total
Procedure protected rights of subject (N=206)	82%	15	3	100%
Procedure improved quality of research (N=191)	28%	53	19	100%
Procedure an unwarranted intrusion on investigator's autonomy (N=212)	1%	16	83	100%
Procedure runs with reasonable efficiency (N=208)	56%	42	2	100
Committee gets into areas not appropriate to its function (N=193)	6%	45	49	100%
Committee makes judgments it is not qualified to make (N=188)	5%	36	59	100%
Procedure impeded progress of research (N=187)	1%	39	60	100%

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*Percentages do not include non-respondents.

Table VI. 3

Attitudes of Investigators Toward Review Procedure and Committees: Other Institutions*

	To a Large Extent	To Some Extent	Not at All	Total
Procedure protected rights of subject (N=135)	64%	35	1	100%
Procedure improved quality of research (N=120)	14%	42	44	100%
Procedure an unwarranted intrusion on investigator's autonomy (N=144)	2%	36	62	100%
Procedure runs with reasonable efficiency (N=139)	49%	41	10	100%
Committee gets into areas not appropriate to its function (N=125)	9%	33	58	100%
Committee makes judgments it is not qualified to make (N=128)	8%	42	50	100%
Procedure impeded progress of research (N=129)	5%	43	52	100%

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*Percentages do not include non-respondents.

Table VI.-4

Suggestions for Improvement: Principal Investigators (Percent of Projects)*

	Type of Institution		
	Children's Hospitals (N= 44)	Other Biomedical (N= 231)	Other (N= 150)
No suggestions	42%	42%	35%
Comments regarding "bureaucratic problems" with review process and their negative consequences for research	12	16	19
Speed up the process; takes too long now	1	6	9
Simplify; too complicated; too much to do	1	3	7
Review procedures are having adverse effects on research, slow it, prevent it, etc.	12	3	4
Less emphasis on details; more on human subject protection	0	-	-
Rules should be consistent across boards; avoid multiple reviews by having a consistent procedure	1	2	-
Review committees are overly protective, extreme in concern for subjects	0	2	1
Timing and scheduling of review causes problems	0	1	-
Parts of review process should be abolished	7	17	10
Be less rigid/more lenient in application of rules and proceudres	2	2	1
Review subject use only; don't review study design and purpose. Should not control research beyond human subject treatment; committee gets into areas and decisions not appropriate to its purpose	1	1	-
Eliminate reviews on previously approved studies, don't review renewals or continuations of projects	0	1	1

(Table continued)

(Table 4 continued)

	Type of Institution		
Continued	Children's Hospitals (N= 44)	Other Biomedical (N= 231)	Other (N= 150)
Do not review studies using materials from previously approved research or materials which would be available even if there were no research	1%	4%	-
Differentiate; more caution when risk/intervention involved; less severe/rigid for more innocuous research; no review for innocuous research	2	8	6%
Eliminate reviews on standard research practices	1	1	-
Be less rigid with research on patients with life threatening conditions and terminally ill patients	0	-	0
Eliminate written/informed consent in some circumstances (for example participant observation and cases where results would be biased)	1	2	3
Change structure and/or authority of review process or review committee	11%	12%	11%
Get help or consultant if the review committee is not able to understand or handle aspects of some proposals	0	4	2
Change or improve the composition of the committee; get different kinds of people; use a different selection process	11	7	5
Give more authority to local boards	0	1	0
The committee is too political	0	-	0
Monitor the review committee for thoroughness, fairness, efficiency.	0	1	0
Have outside authority to which to appeal review committee decision	0	0	-
Abolish the committee, certify investigators, and let them decide	0	1	4

(Table continued)

(Table 4 continued)

	Type of Institution		
	Children's Hospitals (N= 44)	Other Biomedical (N= 231)	Other (N=150)
Give more information to researchers; improve communications between committees and researchers; define, clarify and set guidelines	15%	9%	14%
Need more guidelines in general	0	2	7
Define "informed consent," tell investigators more clearly/specifically what needs to be done to meet "informed consent" requirement; provide sample consent forms	5	2	-
Decide/clarify when written consent must be obtained	0	1	2
Decide/define what research must be reviewed; define "human subject" for review purposes	0	-	1
Define/clarify liability and responsibility	0	0	-
Define/clarify risks and deception	0	0	1
Define/clarify proxy consent	2	0	1
Review committees should disseminate information on what they want/action they've taken and why the action was taken	1	2	3
Should be opportunity for interaction between the researcher and the committee	6	2	3
Need special guidelines on children, fetal research	1	1	-
Training sessions should be provided for the committee members	0	0	-

(Table continued)

(Table 4 continued)

	Type of Institution		
	Children's Hospitals (N= 44)	Other Biomedical (N= 231)	Other (N=150)
Do more to protect human subjects--be stricter	12%	10%	10%
Do job more carefully/be tougher; more strict review	9	3	3
Do more follow-up after review to see that proposed procedures are implemented	0	4	4
Stress privacy and confidentiality for subjects	2	-	0
Simplify consent forms for subject	0	0	1
Insure that all or more research is reviewed	0	1	0
Physician/patient treatment should be reviewed	0	2	1
Miscellaneous and other suggestions	3	6	10

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*Totals will add to more that 100% since investigators could make more than one mention.

Table VI .5

Suggestions for Improvement: Subjects and Proxies

	Percent of Subjects/Proxies* (N= 144)	
suggestions	68%	
rease benefits and reduce risks; improve the k/benefit ratio	4	
Increase benefits to subjects--care/services		1%
Increase benefits to subjects--general		2
Reduce risks; test more thoroughly before human experimentation		1
re and better information to subjects	19	
More, better, or simpler explanation of benefits		1
More, better, or simpler explanation of risks or side effects		1
More, better, or simpler explanation of procedures		1
More, better, or simpler information given--general or other areas		14
Give information on results to subjects and/or proxies		5
nduct of research	8	
Perform procedures more efficiently, be better organized		3
Be more courteous and kind in dealing with subjects; take more time with subjects		5
scellaneous	8	

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*Totals may add to more than 100% since respondents could check more than one suggestion.

2

LAW OF INFORMED CONSENT IN HUMAN EXPERIMENTATION: CHILDREN

George J. Annas
Leonard H. Glantz
Barbara F. Katz
Center for Law and Health Sciences
Boston University School of Law

Contract No. N01-HU-6-2120

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INTRODUCTION

Before an investigator can use any person as a subject in biomedical or behavioral research, he must obtain that person's informed consent. This consent must be voluntary, competent, and understanding.[1] There are two questions that arise in regard to experimentation on children. First, is a child legally capable of giving an informed and understanding consent? Second, do parents have the legal capacity to consent to the performance of research on their children? This Report will attempt to answer both of these questions.

More than a decade ago, the reknowned legal scholar, Paul Freund, wrote, ". . . the law cannot now be expected to yield precise answers to the ethical problems of human experimentation."[2] Unfortunately, in regard to the law respecting research on children, this statement is equally true today.

Research on children has provided society with substantial benefits. Studies of normal mineral and water composition of healthy infants have led to effective parenteral fluid therapy and regimens with which to combat serious complications of diarrheal diseases.[3] Research on healthy children is the only method by which one can establish normal patterns of growth and metabolism.[4] In addition, the Kefauver-Harris amendments to the Food, Drug and Cosmetics Act[5] require that drugs to be distributed in interstate commerce for use in children be tested in children to determine their safety and efficacy. Due to the fact that children are not simply "little people," drug testing on adults does not provide adequate information regarding dosage, contraindications, toxicity, efficacy, or side effects for children.[6]

The beneficial nature of research on children does not, however, establish its legality. Before going on to examine the law regulating therapeutic medical procedures that are performed on minors, we should first examine the issue of how the law has come to define minority.

WHO IS A MINOR?

Under both American and English common law an individual was a minor until he reached the age of twenty-one.[7] Recently, almost all the states have lowered the age of majority to eighteen.[8] It is not entirely clear how it was orginally determined that the attainment of twenty-one years of age should be the dividing line between minority and adulthood.

In Roman law at the time of Justinian there were three age groups that determined legal capacities and incapacities. First, infantia, when the child was incapable of speech, but by 407 A.D. this was fixed at below seven years of age. Second, tutela impuberes ceased at puberty, as a tutor was no longer required when a child could have children. At later law this was fixed at fourteen for males and twelve for females. Third, cura minoris was the reaching of adulthood, and was later set at twenty-five years of age.[9]

Among the barbarian tribes fifteen was both the age of majority and the age of combat. In thirteenth-century France if either the challenger or the challenged in judicial combat (the forerunner of dueling) was under fifteen years of age, there could be no combat.[10] Between the ninth and eleventh centuries, fifteen seemed to be the age of majority in Northern Europe.[11] The basis on which the age of majority was adopted was quite different in Europe and in Rome. In Rome the question was: Had the male "pupil" both understanding and judgment as to acts in law, particularly in relation to property rights? It was presumed these capacities arose at puberty, later set at fourteen. In Europe, the choice of age fifteen seems to be connected to the capacity to bear arms.[12] Apparently, the raising of the age of majority from fifteen to twenty-one was due to the increase in weight of arms. It was not until the late eleventh century that a military revolution involving a mounted knight occurred, and knighthood became a social distinction. In the twelfth century, knights began riding horses into battle and by the thirteenth century, armor became very heavy. The combination of the heavy armor and the use of horses in combat required a stronger and better trained knight, thus requiring extra years of training and physical development.[13]

During this time, however, socage tenants (those who owned and worked land) recognized fifteen as the age of majority, which was later reduced to fourteen. In socage tenure, one came to majority when he was capable of "attaining to husbandry and 'of conducting his rustic employs.'"[14]

Until 1753 when the Marriage Act was passed, a minor could marry at the age of fourteen without the consent of his parents. After the passage of the Marriage Act, this age was raised to twenty-one for males. A statute of Phillip and Mary raised the age when a female could marry without consent from fourteen to sixteen. It seems that this is responsible for fixing the woman's age of consent to sexual intercourse at sixteen.[15]

A commentator who wrote over a hundred years ago acknowledged the fact that setting any one age for the termination of infancy was inequitable, but states that twenty-one years of age is as good as any other.[16] He points out that human life is divided into four periods, each of which is a multiple of seven.

> Natural infancy ends at seven years, puberty begins at fourteen, legal infancy ends at twenty-one years, and the natural life of man is three-score years and ten.[17]

It is generally believed that the legal status of minority offers children certain protections. As Blackstone put it:

> Infants have various privileges, and various disabilities; but their very disabilities are privileges; in order to secure them from hurting themselves by their own improvident acts.[13]

From an historical perspective, this is not readily apparent. Under ancient Roman law a father had the power of life and death over his children until they reached adulthood. He could kill, mutilate, sell or offer his child in sacrifice.[19] Such was also the case in ancient Greece.[20]

In feudal law if a tenant died leaving a minor heir, the lord was allowed the profitable rights of wardship and marriage. The lord had full use of the child's land and had no obligation to render an account to the minor. Upon obtaining majority, the ward had to sue the lord for possession and pay a half year's profit to the lord to receive his own land. Although the minor is protected from squandering his inheritance, it is a rather expensive means of protection.[21]

It has also been argued that a minor's reduced capacity to contract was not for the minor's protection. Under the common law a father was entitled to all the earnings of his child. One way of assuring the father's receipt of these earnings was to prevent the minor from spending them. This was accomplished by rendering the minor incapable of entering into a binding contract. It also protected the father's goods in that the minor could not sell any of his father's property and convert the proceeds to his own use.[22]

According to Blackstone, at common law minors were given the power to enter into a number of serious endeavors. A male at the age of twelve could take the oath of allegiance; at fourteen, he reached the age of discretion and, as discussed above, could consent to or disagree to marriage, could choose his guardian, and, if discretion was actually proved, could make a testament of his personal estate; and at seventeen he could be an executor. A female could be given in marriage or betrothed at seven; at nine she was entitled to dower; at twelve she could consent to or disagree to marriage, and, if found to have sufficient discretion, could bequeath her personal estate; and at seventeen she could be an executrix.

A three-judge Federal District Court in deciding that some minor women are capable of consenting to abortions stated:

> [W]hatever may be the value of conclusive presumptions making the 18th birthday a turning point for such matters as voting, the purchase of liquor, and entering into contracts other than certain contracts for necessaries, . . . we can attach no such factual magic to that birthday.[24]

This short review of how we have come to adopt an age of majority not only demonstrates that one cannot attach any "factual magic" to that age, but that our choice of an age of majority is based on feudal law and custom with no relevance to the needs of a modern society.

As a result of this fact some courts have taken a more operative approach to resolving age of consent problems in certain specific circumstances. Thus, in another case dealing with a minor woman's capacity to consent to an abortion, the Washington Supreme Court held that:

> The age of fertility provides a practical minimum age requirement for consent to abortion, reducing the need for a legal one.[25]

One commentator writing about the criminal responsibility of children also pointed to the arbitrary ages set for determining their criminal responsibility. The general rule is that a child younger than seven is conclusively presumed to be incapable of committing a crime.[26] Between the ages of seven and fourteen a child is presumed to be incapable of committing a crime, but this presumption is rebuttable by the state.[27] The author then discussed the psychological research that has been conducted concerning the development of moral judgment and a sense of justice in children.[28] She concludes that at approximately the age of twelve

> a juvenile should have reached a sufficient degree of maturation when he is able to assume the consequences of his acts. He has then reached a subjective responsibility and acquired consideration of equity, internalized orientation of right and wrong as well as distributive justice. The child younger than twelve years of age should not be presumed to possess a moral development sufficient to be considered as legally responsible.[29]

Whether or not one agrees with this conclusion, this paper has taken a giant step in its approach to rationally setting an age of criminal responsibility. Instead of basing the choice of an age of responsibility on the weight of armor, she attempted to use modern psychological research for some guidance. Basically, the paper states that one cannot commit a crime until one understands the meaning of moral responsibility, and one does not reach this stage until about the age of twelve.

One attempt has been made at rationally setting an age limit on participation in a particular experimental procedure. Proposed Massachusetts regulations state:

Psychosurgery shall not be performed on the following cate-

> gories of patients; a) all patients under the age of thirty [30] years old where there is still the possibility of developmental maturation. . . .[30]

The physiological fact that developmental maturation continues until the age of thirty was used as the criterion for setting this age limit.

Unfortunately, no such analysis exists in regard to consent of a minor to medical treatment. It would be most helpful to know at what age a child obtains a true sense of his body and mind, knows what it means to take risks, knows what it means to be harmed or suffer discomfort, knows how to balance risks and benefits, and so forth. If we had this knowledge it might be possible to rationally determine an age at which most people could give an informed consent to medical treatment and experimentation. In the absence of such an analysis the courts have constructed their own rules, as we shall now examine.

As a general rule, "a surgeon who performs an operation without his patient's consent commits an assault and battery for which he is liable in damages."[31] The law of battery is designed to protect the individual's interest in freedom from intentional unpermitted contacts. In proving battery, hostile intent need not be shown. One is only required to prove the absence of consent to the contact.[32] The problem of providing medical treatment to children is that they are deemed to be legally incapable of giving such consent.[33] Thus, prior to conducting a therapeutic procedure on a child, the consent of the parent is generally obtained. There is case law that would indicate that the giving of such consent is a parental right that is not tied to any protective function. In the only case that analyzes the basis for the parental consent requirement it is said:

> This rule [that a minor cannot consent to medical treatment] is not based upon the capacity of the minor to consent, so far as he is personally concerned, within the field of the law of torts or law of crimes, but is based upon the right of parents whose liability for support and maintenance of their child may be greatly increased by an unfavorable result from the operational procedures upon the part of the surgeon. . . . [S]ince the parents of such a child are responsible for his nurture and training and are liable for his maintenance and support, others will not be permitted to interfere with such relationship or with matters touching the child's personal welfare.[34]

The court in effect is stating that since the parent of a child might be financially damaged as the result of a procedure performed on his child, he must consent before such a result may occur.

In another case[35] an eleven-year-old child died after an operation to remove her tonsils and adenoids. Although there was no parental consent to the operation, the operation was consented to by the child's adult sister. The court held that only the parent could give such a consent and therefore the doctor committed an assault and battery. What is especially interesting here is that the adult sister was in her third year of training as a nurse, and could probably better understand the necessity for, and risks inherent in, the operation, thereby being better able to protect the child's interest. The court was clearly not concerned with protecting the child's interests but in protecting the parents' prerogatives.

It must be noted that the parental prerogative to consent to medical care for the child is not without its limitations. Where it appears that the parents' decision not to consent to medical treatment will cause the child serious injury, the court will intervene to protect the child's interest. Thus, in In re Clark,[36] the parents would not consent to blood transfusions that were necessary in order to treat their three-year-old child who was suffering from second and third degree burns over forty percent of his body. The court found that:

> [The child] has rights of his own - the right to live and grow up without disfigurement.
>
> The child is a citizen of the State. While he "belongs" to his parents, he belongs also to the state. Their rights in him entail many duties. Likewise the fact the child belongs to the State imposes upon the state many duties. Chief among them is to protect his right to live and to grow up with a sound mind in a sound body, and to brook no interference with that right by any person or organization.[37]

The recent lower court cases, Maine Medical Center v. Houle[38] and In the Matter of Karen Quinlan,[39] hold that parents may not order the termination of treatment that is required to keep their children alive, even when the parents believe that such action would be in the best interests of their child. The protective role courts take is amply demonstrated by the *Houle* case where the doctors, agreeing with the parents, stated that withholding treatment would be in the child's best interests.[40] However, as is discussed in detail in the section on proxy consent, the appeals court in the *Quinlan* case has reduced the protective role of the court.

Moreover, where the courts are not presented with a life-threatening situation, the refusal of a parent to give consent will not be overruled by the courts. For example, in *In re Seiferth*,[41] a parent would not consent to an operation on a fourteen-year-old boy that was needed to repair a harelip and cleft palate. Although physicians and social workers claimed that it was important for this child to undergo such procedures, the court refused to overrule the parental judgment.

However, there is some indication from more recent cases that courts are beginning to take a more protective role even where the situation does not threaten the child's life. In *In re Sampson*,[42] a fifteen-year-old boy suffered from Von Recklinghausen's disease which caused a "massive deformity" of the right side of his face. Although he was excused from school as a result of his deformity and had no friends, this condition did not threaten his physical well-being. Neither his sight nor his hearing was affected. Physicians testified that they could not cure the problem, although it could be alleviated, and that the surgery that would take from six to eight hours to perform was "risky." One physician stated that the risk of the procedure would decrease as the child became older because the relative blood loss would be smaller. He suggested that the court wait until the child reached twenty-one years of age so he could make his own decision, and that nothing would be lost by waiting. The court, finding that psychological harm would result from not performing the procedure now, overruled the mother's refusal to give her consent. This decision is some indication of how far a court will go in protecting the interests of the child by limiting the prerogative of the parent.

THE CHILD'S CONSENT TO MEDICAL CARE

While somewhat limiting the parents' ability to make decisions regarding their child's health care, courts and legislatures are at the same time expanding the child's capacity to give consent to such care. A number of doctrines have developed that enable a child to receive health care services without parental consent. First, if an emergency exists, a physician need not wait to receive consent prior to the commencement of treatment. This rule applies to minors as well as adults.[43] However, determining whether or not an emergency exists requires, in at least some cases, a subjective judgment, and if the physician is wrong in his determination, he may be liable for damages.[44]

Second, an emancipated minor may, in some jurisdictions, consent to medical treatment.[45] Children become emancipated by marriage, judicial decree, consent of the parent or failure of the parents to meet their legal responsibilities.[46] In addition, a minor who is self-supporting and lives separate and apart from his parents is often deemed to be emancipated.

It is noteworthy that although some courts and legislatures allow emancipated minors to consent to health care, emancipation does not generally give a minor the rights of an adult. Generally, a minor is emancipated against his parents and not the whole world. That is to say, he is no longer under their control and guidance, and they are no longer obligated to support and nurture the child. When a California court ruled that "an emancipated child is in all respects his own man . . . with the same independence as though he had attained the age of majority,"[47] a commentator wrote that this case made a "radical departure" from the general rule.[48] The general rule is readily stated in the ancient Massachusetts case of The Inhabitants of Taunton v. The Inhabitants of Plymouth,[49] wherein it was held that the emancipation of a son "did not give him capacity to make binding contracts, beyond other infants; or any political or municipal rights, which do not belong by law to minors."[50]

Some statutes merely state that an emancipated minor may consent to medical care.[51] Some statutes are more explicit, stating, for example, that a minor who is fifteen years of age or older, and who is living apart from his parents regardless of duration, and who is managing his own financial affairs, regardless of the source of income, may consent to medical and surgical treatment.[52]

In the absence of a statute some courts have adopted the emancipated minor rule. Thus an eighteen-year-old (the age of majority in this case being twenty-one) who was married, employed, self-supporting and a father, was held to be legally capable of consenting to a vasectomy.[53] The court looked to the age, intelligence, maturity, training, experience, economic independence, and general conduct as an adult in determining the emancipated status of this minor.

Courts and legislatures in adopting the emancipated minor rule have responded creatively to a specific problem. If a minor is living separate and apart from his parents, requiring parental consent would be a serious barrier to the minor's receiving medical treatment. Additionally, since the parent of an emancipated child is no longer responsible for the maintenance and support of that child, a bad result will not increase that parent's obligation.

Finally, the last exception to the general rule is that "mature minors" can consent to receiving medical treatment. In one seventy-year-old case,[54] a seventeen-year-old boy who was accompanied to the hospital by an adult aunt and adult sister, died during a surgical procedure to remove a tumor from his ear. Although his father had not consented to the procedure, the court held that no battery was committed since he was accompanied by adult relatives, and since the boy, who was almost grown into manhood, gave his consent.

In Lacey v. Laird,[55] an eighteen-year-old underwent plastic surgery on her nose without parental consent. One judge in a concurring opinion found that since she was a minor she could not legally consent to the procedure, and therefore a technical battery occurred. However, since the battery was of a merely technical nature only nominal damages, one dollar or less, could be awarded.[56] Another judge, also concurring in the outcome of the case, said that an eighteen-year-old could consent to simple surgical procedures.[57]

In Bishop v. Shurly,[58] a court found that a nineteen-year-old could consent to the administration of a local anesthetic although his mother requested the use of a general anesthetic. And in Younts v. St. Francis Hospital,[59] a seventeen-year-old intelligent minor was allowed to consent to a skin transplant to treat a seriously damaged finger. The court found that she was of sufficient age and maturity to know and understand the nature of the procedure.[60]

Several states have legislatively adopted the mature minor doctrine to a greater or lesser degree.

In Oregon, any person fifteen years of age or older may consent to medical or surgical care.[61] In Alabama, the age of consent to medical care is fourteen.[62] Mississippi has what may be the most liberal statute which states that:

> Any unemancipated minor of sufficient intelligence to understand and appreciate the consequences of the proposed surgical or medical treatment or procedures [may consent to such procedures].[63]

Basically, the mature minor rule states that anyone who is mature and intelligent enough to give informed consent to a procedure can undergo that procedure without parental consent. Or to put it another way, if you can understand the risks you can consent to them.

THE CHILD'S CONSENT TO TAKE RISKS

Under our legal system the capacity of a child to consent to risky undertakings is not novel. Indeed, the doctrine of "assumption of risk" has been applied to minors a number of times. Assumption of risk is a defense in a negligence action. It means that the plaintiff, in advance, has expressly given his consent to relieve the defendant of an obligation of conduct toward him, and to accept the chance of injury from a known risk arising out of the defendant's actions. This doctrine is summarized in the Latin phrase, volenti non fit injuria - to one who is willing no wrong is done.

To successfully invoke the assumption of risk defense the defendant must show that the plaintiff knew and understood the risk he was incurring, and that his choice to incur the risk was entirely free and voluntary.[64] The defendant must not only know the facts that created the danger, but must comprehend and appreciate the danger itself.[65] If one cannot comprehend the risk because of his age, he will not be taken to have consented. Aside from the most exceptional cases, courts do not hold that children cannot assume the risks of certain activities. For example, a California court held that as a matter of law a three-and-a-half-year-old child could not assume risks.[66] But for the most part whether or not a child can assume the risk inherent in a certain situation is a question of fact.

In one Massachusetts case, a ten-year-old child was struck on the head with a golf ball while he was in the process of collecting golf balls that had been hit from practice tees.[67] The court found that the boy had caddied six or eight times before and had been collecting golf balls for about half an hour prior to being struck. With the knowledge derived from this experience, the court found that this child voluntarily exposed himself to a known and appreciated risk, and therefore could not recover damages.

In Porter v. Toledo Terminal Railway Co.,[68] a thirteen-year-old was injured when he rode his bicycle over rotten railroad tracks, and in Centrello v. Basky,[69] a ten-year-old boy fell and caught his hand in a cement mixer while playing near a construction site. In both of these cases the defendants successfully utilized the assumption of risk defense. In another case, a fifteen-year-old high school freshman had his neck broken in a football game.[70] He sued the school system which entered a defense based, among other things, on assumption of risk. The court held:

> One who enters into a sport, game or contest may be taken to consent to physical contact consistent with the understood rules of the game.[71]

Thus, whether or not a child is capable of understanding the risks inherent in undertaking a dangerous endeavor, and whether or not those risks were voluntarily incurred are questions of fact, and the courts do not find that children are never capable of assuming such risks.[72]

In an unrelated line of cases, courts have also found that minors may waive certain constitutional rights. In the Supreme Court case of Haley v. Ohio,[73] which involved a fifteen-year-old, and Gallegos v. Colorado,[74] which involved a fourteen-year-old, the question presented to the Court was the validity of confessions made by these minors. The Court did not hold that fourteen- and fifteen-year-old children could not give their consent, but held that such confessions would be valid where the minor had the counsel of a lawyer, parent, or adult friend. In a 1971 Pennsylvania case the court found that "a fifteen-year-old boy with an I.Q. of 76 and a mental age of eight to eleven-and-a-half was held to have the required understanding of his constitutional rights to render his confession obtained after four hours of interrogation admissible."[75]

In summary, certain points can be made regarding how courts view parental and children's rights to make decisions concerning risk-taking.

1. The general rule concerning majority and the age of consent is not based on a scientific or logical rationale. It is the result of generally irrelevant feudal law doctrine.
2. Parents can consent to therapeutic medical care for their young children.
3. The trend is that older children who can understand the consequences of a therapeutic medical procedure can consent to that procedure.
4. In the area of consent to therapeutic medical treatment courts require either the consent of the minor or of the parent, but not of both.
5. In areas outside the field of medical treatment, courts find that children may consent to take risks or waive rights, but base their decisions on the factual circumstances of the specific case.

NON-THERAPEUTIC EXPERIMENTATION ON MINORS

It has been stated that a resolution of the legal problems surrounding non-therapeutic experimentation on minors is made extremely difficult due to the fact that statutory law is non-existent and case law is largely irrelevant.[76] Unfortunately, this observation is correct. Two questions are presented that must be dealt with. First, since it is generally understood that the law allows a parent to consent to the invasion of his child's body only if such invasion is for the child's benefit or welfare,[77] can the parent consent to the conducting of non-beneficial experimentation on the child? Second, at what point must the child give his consent (or assent) to a non-therapeutic procedure as a pre-condition to its performance?

In trying to answer these questions, Professor Paul Freund has explained how the law approaches novel questions.[78] Law is a basically conservative field - no Nobel Prize is awarded for the most revolutionary judicial decision of the year. The law fears setting a bad precedent. To expand on this point Freund cites F.M. Cornford's book, *Micro-Cosmographia Academica* where it is stated in a somewhat tongue-in-cheek fashion:

> The principle of the dangerous precedent is that you should not now do an admittedly right action for fear that you or your equally timid successors should not have the courage to do right in some future time, which *ex hypothesi* is substantially different but superficially resembles the present one. Every public action which is not customary is either wrong or, if it is right, is a dangerous precedent. It follows that nothing should ever be done for the first time.[79]

Law also tends to generalize on the basis of balancing risks and is deeply protective of human integrity and life. Finally, law is creative and responsive - if the reason for a rule of law ceases to exist, the rule of law should also cease to exist.[80]

With this as a background, we can examine how the problems set forth above have been dealt with.

Codes of conduct that are often referred to for guidance in this area of human experimentation do not directly confront this issue. The Nuremberg Code's first principle is that:

> The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[81]

As the previous examination of the law has demonstrated, minors are generally deemed legally incapable of giving their consent to medical treatment. For emancipated and mature minors, courts and legislatures have decided that they may consent to medical treatment that is rendered for their benefit. It is not at all clear that such minors could consent to non-therapeutic procedures. But assuming that minors are legally competent to give such a consent, they must have "knowledge and comprehension of the elements of the subject matter involved" in order to give such consent. This sounds very much like the mature minor rule discussed earlier. Some argument could be made that under the Nuremberg Code, older minors can and must consent to non-therapeutic research in order for such research to be conducted on them.

It also appears that the Nuremberg Code outlaws proxy consent. It is the consent of the "human subject" that is required, not the consent of a guardian or representative.

The Helsinki Code, on the other hand, states that a subject must give his free consent, but "if he is legally incompetent the consent of the legal guardian should be procured."[82] It is not clear, however, whether or not the guardian's consent is in addition to the incompetent's consent, or if it acts as a substitute for the subject's consent.

The *only* case that exists which deals with this issue is *Bonner v. Moran*.[83] Because it is quoted so often we will explore it in some detail. At the time of the incident involved, John M. Bonner was a fifteen-year-old junior high school student. His cousin, Clara Howard, had been so severely burned that she was a "hopeless cripple." Her aunt (who was also Bonner's aunt) took her to a charity clinic in Washington, D.C. that specialized in plastic surgery. It was decided that a skin graft was required, and a donor with the same blood type as Clara's was sought. After a number of unsuccessful attempts at finding a qualified donor, the aunt persuaded Bonner to go to the hospital for a blood test where it was discovered that he had the same blood type as his cousin. At this time the physician, Dr. Robert Moran, performed the first operation on the boy's side. His mother, with whom he lived, was ill and knew nothing about the procedure. After the operation he returned home and told his mother he was going back to the hospital to get "fixed up." However, once in the hospital more operations were done in order to cut and form a "tube of flesh" from his armpit to his waist. After the tube was surgically formed, it was attached to his cousin forming a literal flesh and blood bond between them. The results were unsatisfactory because of improper blood circulation in the tube, and it was severed after Bonner had lost so much blood he required transfusions. From beginning to end he was hospitalized for two months.

Bonner sued the physician who performed the surgery for assault and battery. The trial court adopted section 59 of the Restatement of the Law of Torts which then stated that if a child were capable of appreciating the nature, extent, and consequences of the invasion, he could consent to the medical procedure. Judgment was accordingly rendered by the trial court in favor of the physician which means that it had to find that the child understood the nature of the procedure and consented to it.

The appeals court began its analysis by noting that the general rule was that a minor could not consent to undergoing a medical procedure, but that there were exceptions to this rule when a minor was emancipated or close to maturity.

> But in all such cases [in which the exceptions apply] the basic consideration in whether the proposed operation is for the benefit of the child and is done with the purpose of saving his life or limb. The circumstances of the instant case are wholly without the compass of any of these exceptions. Here the operation was entirely for the benefit of another and involved sacrifice on the part of the infant of fully two months of schooling, in addition to serious pain and possible results affecting his future life. This immature colored boy was subjected several times to treatment involving anesthesia, blood letting, and the removal of skin from his body, with at least some permanent marks of disfigurement.[84]

The appeals court held that the trial court should have instructed the jury that the consent of the parent was also necessary. The court went on to find that during her son's confinement in the hospital his mother may have learned of what was transpiring, and by doing nothing about it may have ratified her son's consent. If his mother learned about the procedure and publicly expressed pride in her son's courage, such action would have been "tantamount to consent by implication; and that, in the circumstances, would be sufficient."[85]

The court's opinion is both confused and confusing on this point. Clearly the mother could not give her implied consent after the battery occurred. Consent must occur before the fact. The court must be basing its opinion on the mother's ratification of the child's consent, which was given before the second procedure was performed to form the tube of flesh. As a result the appeals court had to agree with the finding of the trial court that Bonner did consent to the procedure.

There is some dispute over the meaning of this case, Curran and Beecher[86] argue that the case holds that non-beneficial procedures "can be legally permitted as long as the parents (or other guardians) consent to the procedure."[87]

Professor Alexander Capron argues that the interpretation "casts more weight onto the opinion that it can bear."[88] Capron suggests that the outcome of the case is based on the court's finding that Bonner was too immature to understand the complications involved, with the issue of lack of benefit "thrown in as a mere addition."[89] He goes on to say that the case is really one of ratification of the minor's consent by the parent, but that it nowhere suggests a parent has independent authority to give consent for a non-beneficial intervention in which a child refuses or is too young to give his consent.[90]

Regardless of scholarly speculation about the meaning of this case, two statements can be made with authority. First, the trial court found as a matter of fact that Bonner understood and consented to the procedure discussed. Second, the appeals court found that as a matter of law, Bonner's mother could ratify his consent. The only conclusion that one can reach with any element of certainty is that if a child and his parent consent to a procedure that does not provide the minor with any benefits, and, indeed, may cause him harm, the procedure may be performed.

One must remember, however, that this case was decided before the Nuremberg Trials were held, and it is conceivable that the outcome would have been different if this case arose after the promulgation of the Nuremberg Code.

There is no case that even suggests that children can consent to non-beneficial research without parental consent. However, the British Medical Research Council, in its statement on children, does suggest that such is the case in England.[91] The statement starts with the premise that in the strict view of English law parents of minors may not, on behalf of the minor, consent to any procedures which carry some risk of harm and do not benefit the minor. It goes on to say that it may "safely be assumed" that no court would regard a child of younger than twelve years of age as having the capacity to consent to "any procedure that may involve him in an injury."[92] Above this age the reality of a purported consent by the minor would be a question of fact, and one would have to show the person involved fully understood the procedures. However

> [e]ven when true consent has been given by a minor. . . . Considerations of ethics and prudence still require that, if possible, the assent of parents or guardians or relatives, as the case may be, should be obtained.[93]

In the English view one cannot perform non-therapeutic procedures that involve risk on any minor under the age of twelve, or on any minor over the age of twelve, unless he can give "true consent." In cases in which such consent is obtained, parental consent is not required by law, although it might be prudent and ethically desirable.

In a limited way the Michigan legislature had adopted a variation of this rule, Section 27.3178(19b) of the Michigan Code states:

> A person of fourteen years of age or older may give one of his two kidneys to a father, mother, son daughter, brother, or sister for a transplantation needed by him, when authorized by order of the probate court. . . .
>
> If the court determines that the prospective donor is sufficiently sound of mind to understand the needs and probable consequences of the gift to both the donor and donee and agrees to the gift, the court may enter an order authorizing the making of the gift.

Thus, the only determination the probate court must make is whether or not the minor can give "true consent" to the procedure. If he can, then the minor will be allowed to consent and the transplant can go forward. There is no mention of the need for parental consent, and the statute would seem to ban organ donation by younger children. This procedure has one advantage over the English rule. In England it would appear that the determination of the existence of a valid consent would occur after the experiment had been performed, whereas in Michigan the before the fact determination better protects all the parties involved.

THE KIDNEY AND BONE MARROW TRANSPLANTATION CASES

The Michigan statute is the result of the existence of a body of case law that deals with the problems of organ transplantation in a confusing and ambiguous manner. Although, as discussed below, these cases are not strictly analogous to the non-therapeutic research situation, they do offer some insights into how courts tend to resolve the issue of proxy consent to non-beneficial procedures.

Kidney transplantation has been conducted with adults since 1954, with the first case involving minors arising in 1957.[94] This case[95] involved nineteen-year-old twins. Although the healthy twin, Leonard, and his parents consented to the procedure, the physicians refused to operate because of the uncertainty concerning the validity of the parents' and the minor's consent to undergo a surgical procedure not for his benefit. To resolve this problem, an action for declaratory judgment was brought before a single justice of the Massachusetts Supreme Judicial Court. During the hearing, psychiatric testimony was offered to the effect that if the sick twin, Leon, died, it would have a "grave emotional impact" on the healthy twin. A finding was made that the operation was required to save the life of Leon and that Leonard had been fully informed and understood the consequences of the procedure and consented. Unfortunately, the court did not stop here and specifically adopt the mature minor rule in this situation. Instead, it went on to find that the emotional disturbance resulting from his brother's death could affect the health and emotional well-being of Leonard for the rest of his life. Therefore the operation was

> necessary for the continued good health and future well-being of Leonard and that in performing the operation the defendants are conferring a benefit upon Leonard as well as upon Leon.[96]

By finding "benefit" to Leonard, the court was able to circumvent the hard issue, since if the healthy donor received a "benefit" the validity of parental consent would no longer be a problem.

This "benefit" theory was used two more times the same year in cases that involved kidney transplants between fourteen-year-old identical twins.[97] In both of these cases the court found that the fourteen-year-olds understood the probable consequences and risks of the procedures, and gave their consent free of pressure or coercion. But the court still went on to use the psychological benefit theory, thereby avoiding the true issue. In all these early Massachusetts cases the courts found that the minors consented, the parents consented, and there was psychological benefit to the donor. If any one of these elements was missing the outcomes might have been different.

Several cases concerning kidney transplants between siblings have arisen since 1957. Perhaps the most discussed is Strunk v. Strunk.[98] In this case the donor, Jerry Strunk, was not a minor but a twenty-seven-year-old incompetent with an I.Q. of 35 and a mental age of six, who was committed to a state institution. The donee, Tommy Strunk, was twenty-eight years old, married, employed and a part-time university student who was suffering from chronic glomerulus nephritis. No other member of the family qualified as a donor due to blood type incompatibility. Because of the apparent lack of benefit to Jerry a court action was instituted, and a guardian ad litem (a guardian appointed for the purposes of litigation) was appointed. The guardian questioned the authority of the state to approve the transplant. Psychiatric testimony was offered that alleged Tommy's death would have an "extremely traumatic effect"[99] on Jerry, and that "Tom's life is vital to the continuity of Jerry's improvement"[100] at the state hospital. The court also found that renal transplantation was becoming relatively common and that over 2500 transplants had been done up to the date of the trial. It found that the chances of the transplant being successful increase when the donor and donee are genetically related and that the risk of transplantation to the donee is small, 0.05 to 0.07 percent. The court then adopted the doctrine of "substituted judgment" in which a court acts in a manner it believes the incompetent would act if he had his faculties. The seriously divided court (4-3) allowed the transplant to go forward, becoming the first case in which such an operation was done without the consent of the donor.

In a strong dissent Judge Steinfeld stated "My sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society."[101] The dissenters, recalling the experiments in Nazi Germany found that guardians must act to "protect and maintain the ward."[102] They found that opinions concerning psychological trauma are "most nebulous," that it is well known that transplants are frequently rejected, and that the life of the incompetent is not in danger but that the surgical procedure creates some peril.[103] According to the dissenters, the ability to fully understand and consent is a prerequisite to the donation of a body part and a transplant should not be done on an incompetent until it can be "conclusively demonstrated that it will be of significant benefit to the individual."[104]

Several years later the case of Hart v. Brown[105] was decided in Connecticut. This case dealt with a kidney transplant between identical twins who were seven years, ten months old. The court found that although Kathleen, the sick twin, was undergoing regular hemodialysis, she could not do so indefinitely and a kidney transplant was required to sustain her life. It also found that, since immunosuppressive drugs would not be required because the twins were identical, such a transplant would be much less risky for Kathleen than a transplant from a different donor, and that there was substantially a 100 percent chance that both twins would live out a normal life upon following the procedure. The family's clergyman felt the decision was morally and ethically sound and a psychiatrist found that a successful operation would be of "immense benefit to the donor in that the donor would be better off in a family that was happy than in a family that was distressed. . . ."[106] The donor was informed of the procedure and "insofar as she may be capable of understanding"[107] desired to donate her kidney. The guardian ad litem also consented. The court specifically noted the limited value of the psychiatric testimony but instead found that

> [i]t would appear that the natural parents would be able to substitute their consent for that of their minor children after a close, independent and objective investigation of their motivation and reasoning. This has been accomplished in this matter by the participation of a clergyman, the defendant physicians, and attorney guardian ad litem for the donee, and indeed, this court itself.[108]

It was also found that this procedure was not "clinical experimentation but rather medical treatment."[109] The court held that

> natural parents of a minor should have the right to give their consent to an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity.[110]

The right to consent on behalf of a minor was given to the parent as long as the parents' motivation was proper.

In a Georgia case, the court substituted its judgment for a moderately mentally retarded fifteen-year-old girl who was to serve as a donor for her dying mother and permitted the transplant.[111]

There are two recent cases in which organ donation by a minor was not permitted. In the first, In re Richardson,[112] the prospective donor was a seventeen-year-old mental retardate with a mental age of three or four, and the prospective donee was his thirty-two-year-old sister, Beverly. An examination of the court's use of the facts in this case is instructive. It found that although a kidney transplant would be beneficial, it was not immediately necessary to preserve Beverly's life. In the first place, there was evidence that she could be sustained indefinitely by kidney dialysis. Second, although Roy would be the best donor available, as there was only a 3-5 percent chance of rejection with his kidney, there were other donors that could donate with a 20-30 percent chance of rejection. And if these were rejected, other transplant procedures could be done. Thus, a transplant from Roy might be the best alternative for Beverly, but there were other, if less desirable, options open to her. The court discussed the Strunk case but found that Louisiana law differs from Kentucky law in that the law of Louisiana "is designed to promote and protect the ultimate best interests of the minor."[113] Under Louisiana's statutes, a minor is not allowed to make any inter vivos transfers of property and a parent is absolutely prohibited from transferring a minor's property. The court reasoned that if the law affords such protection against intrusion into a "comparatively mere" property right, it was inconceivable that the minor's right to be free from bodily intrusion would be any less protected.[114] The argument that Roy would benefit from the procedure because Beverly could care for him after his parents died was rejected as "highly speculative . . . and highly unlikely."[115] The fact that the transplant was the most desirable course of action for Beverly was not enough to convince the court of equity to permit the transplant, since less detrimental alternatives were available. But from the legal analysis performed by the court, even if a transplant from Roy was the only way to keep Beverly alive, it would not have had the authority to permit such a transplant.

In the second case, the Wisconsin Court resolved the problem in a similar manner. In this case, In re Pescinski,[116] a petition was filed with the court asking it to permit a kidney transplant from Richard, a thirty-nine year-old catatonic schizophrenic who had been institutionalized for sixteen years and who had a mental age of twelve, to his thirty-eight-year-old sister who was the mother of six minor children. The physician involved said he would not use her parents, who were aged seventy and sixty-seven, since "as a matter of principle"[117] he would not do the operation on a person over sixty. The physician also refused to use a kidney from any of her minor children as a matter of his "own moral conviction."[118] Another forty-three-year-old brother who a a dairy farm and ten children refused to be a donor because there would be no one to take care of his farm. Additionally, he said he had a stomach problem that required a special diet, and a rupture on his left side. The court's opinion implied that there were a number of competent, healthy potential donors, who were excluded for "moral reasons" or for personal reservations, and who were not asked or did not volunteer to donate their kidneys because of the existence of Richard.

The court held that since Richard did not consent to the procedure, it could not be done.[119] Additionally, a guardian must act "loyally in the best interests of his ward"[120] and there was absolutely no evidence here that any interests of the ward would be served. The concept of substituted judgment was forthrightly rejected.[121] In summarizing its opinion the court stated:

> An incompetent particularly should have his own interests protected. Certainly no advantage should be taken of him. In the absence of real consent on his part, and in a situation where no benefit to him has been established, we fail to find any authority for the county court, or this court, to approve the operation.[122]

Following this line of kidney transplant cases, a separate but similar line of cases resulted from the advent of bone marrow transplantation procedures.[123] The bone marrow cases provide less of a physical intrusion into the donor's body as no body cavity is opened, and unlike kidneys, the bone marrow regenerates itself. The donor is subjected to as many as 200 aspirations of the pelvic bone with a needle specially designed to remove bone marrow.[124] The Attorney General of the state of Washington has determined that written consent of the guardian is sufficient to authorize a bone marrow donation by a minor.[125]

The practice in Massachusetts, however, is still to acquire a court decree prior to the transplant. The court that created the "psychological benefit" mischief is currently dealing with the problem in a more straightforward manner. Thus in Rappeport v. Stott,[126] the judge held that a seventeen-year-old was "capable of consenting to the proposed procedure," and did not bother to find that he received psychological benefit.

The most illuminating bone marrow transplant case is probably Nathan v. Farinelli,[127] because of its forthright approach. Toni Farinelli was a healthy six-year-old and her ten-year-old brother, William, was suffering from aplastic anemia, which, left untreated, is fatal in eighty-five percent of the cases. The parents consented to a bone marrow transplant but the physicians refused to operate in the absence of a court authorization. The court found that the risk to Toni was minimal, but also found that she would receive no benefit. The petitioners took the standard approach and called a psychiatrist as a witness. Surprisingly, she testified that she would be speculating if she ventured any opinion about the psychological effect of either allowing or preventing the intended donor from furnishing the bone marrow.[128] The court appreciated her honesty and found that

> [t]o require a finding of benefit to the donor, and particularly to accept a psychological benefit as sufficient, often seems to invite testimony conjured to satisfy the requirement by words but not by substance.[129]

The court also rejected the "substituted judgment" theory as being irrelevant in these situations.[130]

> It is the court's opinion that a better approach to the issue involved in this case is to consider that the primary right and responsibility for deciding the delicate question of whether bone marrow should be taken from Toni and transplanted in William is that of the parents with reference to both children.[131]

The requirement that the parents' decision be reviewed arises out of the possible conflict between the parents' responsibility for the care and custody of one child, and their similar responsibility for the other. In what can serve as a summary of all these cases, the court wrote, "It would be more truthful to recognize that the parents themselves are making decisions for their children,"[132] and are not substituting their judgment for that of the child. Finding that the parents' decision was "fair and reasonable" the court permitted the procedure to be done.[133]

The reason for setting out these cases so extensively is that, with the exception of Bonner, they are the only cases that deal with consent to non-beneficial procedures. But we can learn a number of lessons from these cases, as diverse as they may be, that are applicable to research conducted on children.

Although never explicitly stated, courts will permit parents to consent to therapeutic research on children, even where the risks are high, if the benefits are great. In the bone marrow transplant cases, the transplanted bone marrow might cause adverse reactions in the recipient's body. This condition, called graft-versus-host disease, can lead to an agonizing death.[134] However, since the experimental procedure might save the life of a doomed child, no question is raised as to the ability of the parent to consent on his behalf.[135]

As to these cases' importance in regard to non-therapeutic experimentation, we must look at the differences between the transplant cases and non-therapeutic research. First, the procedures that were performed on the donors in the transplant cases were not experimental. Neither the removal of a kidney nor bone marrow aspiration is considered an innovative procedure.

Second, in the average non-therapeutic research setting, parents will not have to struggle with the conflict of interest problem. One commentator has pointed out that one reason why experimentation must be more closely regulated than therapy, is because during therapy the doctor sees the patient as an end and not a means, and in non-therapeutic experimentation the subject is seen as the means and not the end.[136] In the transplant cases the parent must also view the donor child as a means, and the cure of the ill child as the end. As a result, the parent's role as the protector of the donor child might be negatively influenced. Courts should be especially aware of this in cases in which the donor is mentally ill or retarded and it may be suspected that parents and physicians may not value the life of the donor as highly as the life of the donee. This is made all the more apparent by the fact that in all the transplant cases involving mentally ill or retarded adults or children, all the mentally ill or retarded individuals were donors, never recipients. Indeed, during the hearings in the Strunk case, the Director of the Renal Division, University of Kentucky Medical Center, testified that if something should later happen to the retarded donor's remaining kidney, based on selection criteria at the Medical Center, the donor would not be eligible for either hemodialysis or transplantation.[137] Because of the possibility of exploitation, it is not surprising that the two cases in which the courts denied permission to conduct the transplant involved a mentally retarded and a mentally ill individual.

In the absence of such a conflict, parents should be better able to protect the interests of their child when an investigator asks their permission to use their child as a subject in non-therapeutic research.

It might be presumed that parents could put all their energies into protecting their healthy child, because they need not be concerned about the welfare of a sick child.

Both parents and children might be better able to make protective decisions concerning the child's welfare in non-therapeutic research than in the transplant situation because no duress should exist. When a transplant is needed by a sick child, and the healthy child is the only available donor, one essentially communicates the point to both the parent and the child that unless consent is received from all concerned, the child or sibling will die. Truly voluntary consents are hard to imagine in such a situation.[138] But where neither the parent nor child receives any benefit, duress should be entirely absent.

From this analysis it would appear that children involved in non-therapeutic research need *less* outside protection than transplant donors.

But if one looks behind the logic involved in these cases one can see why these cases are resolved the way they have been. The transplant cases revolve around the power of the family to protect its own members. When a child is sick the family as a unit is permitted to use its resources and make sacrifices to help the sick member. All the courts agree on one point, however, the general rule is that parents must act in the best interests of their children and not subject them to harmful situations. The courts that permit transplants have gone through incredible feats of mental gymnastics, such as finding benefit where none exists, to overcome the general rule. The *Farinelli* case, tired of these maneuvers, directly confronted the issue and held that the family could protect its members, and made its decision on that basis.

In addition, as discussed above by Freund, in the transplant cases the courts are balancing risks and being deeply protective of life. Where the risks are relatively minimal and a life hangs in the balance, the courts will decide in favor of life.

PROXY CONSENT

All the transplant cases have had to struggle with the problem of proxy consent to non-beneficial procedures. As has been demonstrated by these cases, the issue of who can consent to non-beneficial procedures that are to be conducted on another person is far from resolved. Part of the problem springs from the fact that the very term "proxy consent" is a contradiction in terms. If the major purposes of the doctrine of informed consent are to protect self autonomy and self determination, it is difficult to conceptualize how these very personal rights can be exercised by a third party. The courts have confused the matter even more by not clearly setting forth the grounds upon which they have validated the exercise of proxy consents.

There are three tests courts have used in determining whether or not proxy consent on behalf of an incompetent organ donor is valid - the "substituted judgment" test, the "best interests of the donor" test, and the "fair and reasonable" test.[139]

The substituted judgment concept has a lengthy history that predates Strunk, the first transplant case to adopt the doctrine. It appears to have originated in the 1816 English case of Ex parte Whitbread,[140] in which it was held that a portion of the money in the estate of a "lunatic" could be given to his next-of-kin to rescue them from poverty. In deciding that such a use of the incompetent's resources was permissible although he did not directly benefit from the use of the funds, the court looked "at what it is likely the lunatic himself would do, if he were in a capacity to act. . . ."[141] The court merely placed itself in the position of the incompetent and determined how it thought he would act if he were competent. There was apparently no evidence as to how this specific individual truly desired to have his funds used in this circumstance, but the court decided he would have acted in the same fashion as would a reasonable person.

More recent American opinions have required courts to actually try to determine how the particular incompetent would act in a given situation. In so doing, courts have imputed to incompetents motives of charity, altruism, self-interest, and the desire to reduce estate taxes in upholding gifts from their estates.[142] Courts have also taken into account evidence that the incompetent had previously made gifts to a particular person or persons, or had stated an intention to make such gifts prior to becoming incompetent.[143] In addition, it has been inferred by courts that the incompetent would have made such transfers to his immediate family, and sometimes has extended this inference to more distant relatives.[144]

Thus, the historical basis for the substituted judgment test is a line of cases dealing with the transfers of property from an incompetent to a family member who was in need of funds. The question that presents itself is whether or not this principle should be transferred to the organ donation and non-therapeutic research situation. Certainly the court in the *Strunk* case had no problem making this conceptual leap. However, an invasion of a person's body is a more serious undertaking than the invasion of a person's property under our system of jurisprudence. Additionally, determining what a "reasonable person" would do when confronted with the decision to donate an organ is not an easy task. In the Pescinski case, it was noted that a number of possible donors did not volunteer to donate a kidney to a relative. However, in the cases of competent donors, we do see relatives readily donating their organs to members of their immediate families who suffer from kidney disease. In one study of kidney donors, it was discovered that fourteen out of the twenty questioned stated that their decision to donate was made in a "split second" or "instantaneously" after learning of the need for the donation.[145] It appeared that their decision-making process was "irrational" and could not be said to meet the requirements of informed consent.[146] If this is an accurate indication of how "reasonable people" make their decision to donate their kidneys to relatives, a court substituting its judgment on behalf of an incompetent could use this information as guidance in determining how a "reasonable person" would act in a similar situation. Thus, if a court found that "reasonable people" act irrationally when faced with the decision to donate an organ, and often agree to donate an organ without taking the risks into account, it could use this finding to permit the donation by the incompetent. Although the Wisconsin[147] and Louisiana[148] courts have rejected the use of the substituted judgment test in regard to kidney donations, one commentator has suggested that such an approach deprives the incompetent of the benefits that might be derived from donation.[149]

Regardless of the validity of the substituted judgment doctrine as applied to the organ transplant situation, it would seem to have no bearing in the non-therapeutic research situation. Both the historical basis for the doctrine and its recent applications indicate that the doctrine is only to be used to benefit a close relative in need of either funds or a body organ. Non-therapeutic research is usually conducted to benefit society in general at some future date, and therefore the doctrine would not seem to be applicable. In addition, it is far from clear that "reasonable people" generally consent to undergo, for the benefit of society as a whole, non-therapeutic experimental procedures that carry a risk of harm.

The second test under consideration, the "best interests" test is closely allied with the substituted judgment doctrine. Under this test, one has to demonstrate that the donor will directly benefit from the donation of an organ. This is the test that was utilized in the first three kidney donation cases involving minors.[150] In these cases, it was found that the donors would receive a "psychological benefit" as a result of donating a kidney to their sick twin. By establishing the presence of a benefit, the court was able to avoid the difficult issue of the validity of proxy consent to non-beneficial procedures. Once a benefit to the donor was established, there was no question that the parents could give their consent. In the Strunk case, the court found that the survival of the sick sibling was necessary for the "treatment and eventual rehabilitation" of the incompetent and institutionalized donor.[151] In the Richardson case, it was argued that the transplant was in the best interests of the donor because, if the sick sibling survived, she could care for the incompetent after the deaths of their parents.[152] The court rejected the argument as being both "highly speculative" and "highly unlikely."[153] The best interests doctrine would also appear to have no applicability to the non-therapeutic research situation. It is difficult, if not impossible, to think of how subjecting a child to non-therapeutic research that carries a risk of harm could be in that child's best interests. This doctrine, would, of course, apply to therapeutic research.

Finally, the "fair and reasonable" test has been adopted by one court in Massachusetts in the case of Nathan v. Farinelli.[154] As discussed earlier, the court found that the parents of a minor donor have the primary responsibility in deciding whether or not their child can serve as a donor in a bone marrow transplantation procedure. The only determination the court made was to decide whether or not the parents' decision was fair and reasonable in the particular circumstances.[155]

This test would be applicable in the non-therapeutic research setting. It is conceivable that the parents' decision to subject their child to a non-therapeutic research procedure that did not involve any risk or involved a very minimal amount of risk could be deemed to be fair and reasonable. The problem with this test is that it is very subjective, since what may appear to be fair and reasonable to one person might be considered unfair or unreasonable by another.

The most recent, and perhaps the most drastic, proxy consent case involves the right of a parent to terminate medical procedures that are required to sustain the life of his comatose adult child. In this case, In the Matter of Karen Quinlan,[156] Joseph Quinlan, Karen's father, petitioned the lower court to appoint him guardian of the person and property of his comatose daughter, with the specific authority to order cessation of life-sustaining procedures. The lower court denied this petition[157] but was reversed by the New Jersey Supreme Court. The Supreme Court found that Karen's right to privacy would enable her to order cessation of extraordinary life-sustaining procedures if she were competent to do so.[158] It went on to find that she was grossly incompetent to assert this right, but that such a right could be asserted on her behalf by a guardian.[159] The court reasoned that not to permit such action by the guardian would be to deprive Karen of her right to privacy. The court found:

> The only practical way to prevent destruction of the right [to privacy] is to permit the guardian and family of Karen to render their best judgment, subject to the qualifications hereinafter stated, as to whether she would exercise it in these circumstances. If their conclusion is in the affirmative this decision should be accepted by a society the overwhelming majority of whose members would, we think, in similar circumstances, exercise such a choice in the same way for themselves or for those closest to them.[160]

This would seem to be an acceptance of the substituted judgment doctrine. The court also seems to accept the fact that it must evaluate the "interests" of the patient as seen by her guardian.[161] This would appear to be some recognition of the best interests test. Finally, the court seems compelled to examine the "motivation and purpose" of the guardian, which might indicate that it is concerned with whether or not he would act in his ward's best interest, and in a fair and reasonable manner. Thus, the court touched on all the tests, although it seemed to adopt the substituted judgment test. As an additional precaution, the court requires the incompetent's physician and an "ethics committee" to be in agreement with the guardian's decision.[162] Regardless of these additional safeguards, the Quinlan case would seem to expand the power of a parent or guardian to substitute his judgment for his child or ward. However, the facts of this case are very different from either the organ transplant situation or the non-therapeutic research situation, and therefore the holding cannot be applied to those instances.

We should not expect that courts will permit non-therapeutic research on children without their consent, where there is a chance that harm will occur. At this point one must recall the pronouncement in In re Clark that:

> [T]he fact the child belongs to the state imposes upon the state many duties. Chief among them is to protect his right to live and to grow up with a sound mind in a sound body, and to brook no interference with that right by any person or organization.[163]

Although someday we might all benefit from the results, no specific life will be immediately prolonged by such participation. One commentator has pointed out that allowing non-beneficial procedures to be performed on minors without their consent, but requiring the consent of adults prior to such procedures being performed on such adults, enables us to force children to participate in activities that may harm them, but not force adults to participate in similar programs.[164] One might analogize this to lowering the age of conscription to include only those from birth to eighteen. It can be concluded that neither parents nor courts can consent to non-therapeutic research on minors who have not also given informed and voluntary consent. The consent of the minor to non-therapeutic research that puts him at risk of harm is essential.

Hopefully, the question of the limits of parental proxy consent to non-therapeutic research on children will be resolved by a case now pending in California, Nielson v. Board of Regents.[165] In this case, the plaintiffs are seeking to bar the use of normal, healthy infants, ranging in age from two months, to four years, as controls in an asthma research project. Blood samples were to be drawn and drugs injected to determine the children's tolerance to such substances and stresses.[166] The study was to last five years and the parents were to be paid $300 per year for their children's participation.[167] There is no question that the children cannot give their consent due to their young age, and the complaint alleges that California law prohibits parents from consenting to such research. California Penal Code § 273(a) states:

> (1) Any person who, under circumstances or conditions likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering, or having the care or custody of any child, willfully causes or permits such child to be placed in such situation that its person or health is endangered, is punishable by imprisonment in the county jail not exceeding one year, or in the state prison for not less than one year nor more than 10 years.
>
> (2) Any person who, under circumstances or conditions other than those likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering or having the care or custody of any child, willfully causes or permits the person or health of such child to be injured, or willfully causes or permits such child to be placed in such situation that its person or health may be endangered, is guilty of a misdemeanor.

One writer argues that the complaint does not go far enough.[168] The experimental group consists of children who are "at-risk" of becoming asthmatics, as indicated by their family medical histories. The complaint does not allege that parents cannot consent to the participation of these children. These children are not now ill, and the drugs given to them are not designed to cure them of a present illness. If they do become ill this research may be of help to them at that future time, but it is argued, at the moment it must be deemed non-therapeutic: And therefore parents may not give consent to their child's participation.

The difference between therapeutic and non-therapeutic research is not obvious. In testing the polio vaccine which was supposed to prevent a clinically rare disease, but could, and sometimes did, cause the disease, one might ask, "Were these children subject to therapeutic or non-therapeutic procedures?" None were being treated for an existing condition, and the large majority would never contract the disease. Or were the controls who did not receive the vaccine the ones who were put at risk?[169]

Some research may have elements of both therapeutic and non-therapeutic procedures. In one study of phenylketonuria (PKU) and diet, a two-year-old child who could not stand, walk or talk, and who spent her time crying, groaning and banging her head as a result of PKU, was given an experimental diet. Within a few months she improved greatly. This was clearly therapeutic. To establish that the improvement was due to the special diet rather than to natural development, the investigators added five grams of L-phenylalanine to the diet without telling the child's mother, so that her observations would not be biased. The child rapidly deteriorated. Could the determination that the diet made the difference in the developmental progress be considered therapeutic? The diet is both expensive and restrictive and it would be an injustice to keep the person on the diet forever if it wasn't required.[170]

A SHORT NOTE ON BEHAVIORAL RESEARCH

This paper does not deal with the problems of behavior modification in children because this issue is covered in the section on the problems of research on institutionalized mental patients. In dealing with non-institutionalized behavior modification in children, the analysis regarding biomedical research would apply. Thus, research on drugs that control hyperkinetic activity should be viewed no differently from research on drugs to control a physical ailment. The more serious problems relating to the use of aversive techniques, token economy and other invasive techniques occur in institutional settings on both children and adults and are dealt with in that context.

SUMMARY

1. The general rule is that one must obtain the informed and voluntary consent of the subject prior to his participation in biomedical or behavioral research.

2. There are no decided cases or statutes that specifically deal with the problem of the validity of the consent of the parent or child to participation in non-therapeutic research.

3. The one case that comes closest to confronting this problem, Bonner v. Moran, held that if the trial court found that both a fifteen-year-old and his mother consented to his undergoing a procedure that posed serious risks to his health, while offering him no benefits, that such consent would free the physician from liability.

4. Although in the kidney and bone marrow transplantation cases courts permit parents to consent to non-beneficial procedures on behalf of the minor donors, the cases are factually distinguishable from the non-therapeutic research situation. In the transplantation cases, one family member acts to save the life of another family member. Even in these cases, courts generally require some sort of consent from the donor, and require prior court review of the parents' decision to permit the transplant.

5. Courts have not questioned the right and ability of parents to consent to the performance of therapeutic research on their sick child.

6. Courts are expanding their role as the protectors of the best interests of the child.

7. Courts will closely scrutinize the facts of a particular situation

to ensure that one who is not capable of protecting his own interests is not being exploited.

8. Parents have the legal duty to protect the health, well-being and best interests of their children.

9. Courts have found that with adequate safeguards children are capable of waiving important rights, and can consent to incurring serious risks.

CONCLUSION AND RECOMMENDATIONS

1) Therapeutic research - Where research is designed to cure a specific disease or condition from which the child is suffering, and no other drug or procedure is available to treat such condition or disease, or the existing procedure is more dangerous or produces greater discomfort than the proposed procedure, such therapeutic research should be allowed to be conducted with the informed consent of both parents, or one parent if both are not available.

In such a case the parents are consenting to therapy. Or to put it another way, they are consenting to a procedure that is carried out with the purpose of furthering the best interests of the child. As such, the law will enable parents to consent to such procedures. Although the consent of one parent would probably be sufficient, because of the experimental nature of the procedure it would be prudent to allow both parents to decide that the standard procedure is not to be used, since the new procedure might not be efficacious.

2) Non-therapeutic research - For non-therapeutic research that carries a risk of harm, such procedures should only be done when the risks are extremely small and the benefits to society are very great. When it has been determined that the risk-benefit ratio of a certain procedure falls into this category, courts, performing their own balancing test, would probably uphold the parental right to consent to their child's participation in such a study. What constitutes a high-risk procedure is not readily determined. Is a high-risk procedure that which has a one-in-a-million chance of causing death, or one that

has a fifty percent chance of causing a headache? Though no definitive answers are available, the Ethical Review Board, the Institutional Review Board and the Consent or Protection Committees should all be given the authority to make an independent determination of this issue regarding any proposed research.

When a minor is capable of understanding these procedures his consent should also be required. Or, in other words, he should have the absolute right to refuse to participate in such non-therapeutic procedures. The problem is setting an age at which a minor has such understanding of risk-taking, benefits and harm, and is able to weigh these factors, so that he can give a truly informed consent. One can establish a subjective rule and say that a minor of sufficient intelligence and maturity to understand the consequences of the proposed experimental procedure may consent to such procedures. Investigators would probably be unhappy with this because they would have to make such a determination, and if they are wrong, liability might result. However, investigators must also make this determination in adults. If an adult is incapable of understanding the risks inherent in undergoing an experimental procedure, an investigator cannot get his informed consent.

Alternatively, one could have all minor subjects of this type of research screened by a protection committee which would make the determination. Or we could ask the courts to make such a finding, as is the case in Michigan in regard to kidney transplants.

The advantage of setting a specific age at which a child can participate or refuse to participate is its objective nature. But it must not be set too low. Draft proposed federal regulations state that research cannot be done on a child above the age of six without his consent.[171] A child of this age will probably agree to do almost anything an authority figure requests. Although it gives the child the right to say no, it is probably a right that will not be forcefully exercised. The age should be set higher, hopefully on a scientific basis with the help of experts in child development. The Michigan statute uses the age of fourteen, Professor Curran suggests fourteen,[172] and the British Medical Research Council suggests twelve.[173]

The consent of both parents should be required if both are alive. Since their child might be injured, they should be able to veto his decision since such an injury would have a negative impact on them and would not benefit their child in any way. In addition, since it can be presumed that they will protect the interests of their child when no conflict exists, their counsel should be sought, and their protective role utilized. Children who have no parents and institutionalized children should not be allowed to participate in such studies. The institutionalized child has the duel burden of his minority and the effects of institutionalization.

Children below the age of consent that has been selected, or who are too young to understand the nature and consequences of a procedure, may be subjects in non-therapeutic research when there is no chance of harm occurring, or, as discussed above, the risks are minimal. When harm cannot occur, the need for consent declines considerably, and one need not worry about the exploitation of the child. Of course, the consent of the parents should still be required.

Federal regulation of research can only add to the protections already required by state law. Thus, if California outlaws all non-therapeutic research on minors, federal regulations cannot permit such activities in that state.

We believe these recommendations are fair. They protect the children-subjects as well as the parents of these children, but do not unduly burden the research community. Such regulation of research will permit it to continue without exploiting the children who deserve our utmost protection.

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121. *Id.*

122. *Id.* at 182.

123. *See*, Baron, Botsford and Cole, Live Organ and Tissue Transplants from Minor Donors in Massachusetts, 55 B.U.L. Rev. 159 (1975).

124. *Id.* at 164 n.20.

125. *Id.* at 162 n.16.

126. Civ. No. J74-57 (Mass. Aug. 28, 1974).

127. Civ. No. 74-87 (Mass. July 3, 1974).

128. Id. at 7.

129. Id.

130. Id. at 8-9.

131. Id. at 10.

132. Id.

133. It is noteworthy that this court ordered both parties to try to procure insurance that would compensate the donor for any harm that might come to her. Id. at 12. The court must have realized that although the requirement of informed consent serves to protect the child, there are other mechanisms which would offer additional protection.

134. See, Baron, et al., supra note 123, at 159-160 n.4, citing Bach and Bach, Immunogenetic Disparity and Graft-Versus-Host Reactions, 11 Seminars in Hematology 291 (1974).

135. Although at least one Massachusetts Probate Court judge appoints a guardian ad litem for the donee child as well as for the donor child, the role of the donee's guardian is not clear. See, Baron, et al., supra note 123, at 163 n.19.

136. See, Freund, supra note 2, at 689.

137. Savage, Organ Transplantation with an Incompetent Donor: Kentucky Resolves the Dilemma of Strunk v. Strunk, 58 Ken. L.J. 129, 146 (1970).

138. See, Sharpe, The Minor Transplant Donor, 7 Ottowa L. Rev. 85, 98 (1975).

139. See, Baron, et al., supra note 123, at 169-181. A fourth test would be to determine if the donor is sufficiently mature to personally consent.

Since this does not involve proxy consent it is not discussed here.

140. 2 Mer. 99 (1816).

141. *Id.* at 102.

142. Robertson, Organ Donations by Incompetents and the Substituted Judgment Doctrine, 76 Col. L. Rev. 48, 58 (1976).

143. *Id.* at 59-60.

144. *Id.* at 60-61.

145. Fellner and Marshall, Kidney Donors - The Myth of Informed Consent, 126 Am. J. Psychiatry 1245 (1970).

146. *Id.*

147. *Supra* note 116.

148. *Supra* note 112.

149. Roberston, *supra* note 142, at 70.

150. *See*, Curran, *supra* note 94.

151. *Supra* note 98, at 147.

152. *Supra* note 112, at 187.

153. *Id.*

154. *Supra* note 127.

155. *Id.* at 10-11.

156. Sup. Ct. of New Jersey, A-116 (1976).

157. *Supra* note 39.

158. *Supra* note 156, at 33-38.

159. *Id.* at 38.

160. *Id.* at 38-39.

161. *Id.* at 37.

162. *Id.* at 58-59.

163. 185 N.E.2d at 132.

164. Baron, _et al._, _supra_ note 123, at 176.

165. Civ. No. 665-049 (Super. Ct. San Francisco. Cal., filed Aug. 23, 1973).

166. _See_, Mitchell, _supra_ note 82, at 929.

167. _See_, Lowe, _et al._, _supra_ note 3, at 470.

168. Mitchell, _supra_ note 82, at 930-931 n.49.

169. _See_, Lasagna, Special Subjects in Human Experimentation, 98 Daedalus 449,458 (1969).

170. Bickel, Gerrard and Hickmans, Influence of Phenylalanine Intake on Phenylketonuria, 2 The Lancet 812-813 (1953), reprinted in Katz, Experimentation with Human Beings, 958-959 (1972).

171. 38 Fed. Reg. 31746 § 46.27(e), Nov. 16, 1973.

172. Curran and Beecher, _supra_ note 86, at 82.

173. _Id_. at 80.

3

THE ETHICS OF NON-THERAPEUTIC CLINICAL RESEARCH ON CHILDREN

and

PROXY CONSENT IN THE MEDICAL CONTEXT: THE INFANT AS PERSON

William G. Bartholome

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THE ETHICS OF NON-THERAPEUTIC CLINICAL RESEARCH ON CHILDREN

The purpose of this paper is three-fold: First, I will briefly review some of the recent literature dealing with this subject (1,2,11,12,15). I will then examine in detail a recent article by Richard J. McCormick, entitled "Proxy consent in the experimentation situation" (13). And, finally, I will draft a proposal for guidelines for such research.

Before undertaking this analysis, it is helpful to define what is meant by the term "non-therapeutic clinical research." I will use the National Institutes of Health definition:

> Clinical research means an investigation involving the biological, behavioral, or psychological study of a person, his body or his surroundings. This includes but is not limited to any medical or surgical procedure, any withdrawal or removal of body tissue or fluid, any administration of a chemical substance, any deviation from noraml diet or daily regimen, and any manipulation or observation of bodily processes, behavior or environment (6, p,31379).

These N.I.H. guidelines further distinguish four categories of clinical research:

1. Studies which conform to established and accepted medical practice with respect to diagnosis or treatment of an illness.

2. Studies which represent a deviation from accepted practice, but which are specifically aimed at improved diagnosis, prevention, or treatment of a specific illness in a patient.

3 Studies which are related to a patient's disease but from which he or she will not necessarily receive any direct benefit.

4. Investigative, non-therapeutic research in which there is no intent or expectation of treating an illness from which the patient is suffering, or in which the subject is a "normal control" who is not suffering from an illness but who volunteers to participate for the potential benefit of others (6, p.31379).

Although there is considerable over-lap between categories 3. and 4., the emphasis in this paper will be on category 4. experiments. An argument can be made that studies in category 3. are "not necessarily" therapeutic, but that direct medical benefit can (and often does) accrue to subjects of such investigations. Although the ethical considerations involved are more complicated than those in categories 1. and 2., they are similar enough to warrant their discussion under the rubric of therapeutic research.

It is also necessary to attempt to define what is meant by the term children. Legal distinctions, although primarily concerned with the question of legal status of minors, are helpful. For the purposes of this discussion I will use the age span 14-16 years as the upper limit of the definition of children. I realize this is arbitrary and based on no significant ethical ground, but rather on the legal opinion that this is the age range when it becomes possible to obtain informed consent (2). Obviously, except in the case of emancipated minors, parental consent should be required in addition for clinical research up to age 18-21.

I will also use another age distinction in my discussion. Once again, the ethical grounds are uncertain, but I will use the age span 5-7 years as what is traditionally referred to as the "age of reason." In the proposals which conclude this essay, I will show why such a distinction is necessary.

In virtually every discussion of clinical research, the key concept, the sine qua non is that of consent. Consent is portrayed as the only means by which the invasion and infringement on personal inviolability involved in research can be justified. Although many have studied the process of obtaining "informed consent" and found it wanting (8,9,19), no author is willing to build the argument for experimentation from a different base. The voluntary nature of informed consent is seen as the only moral justification for involvement of humans in research.

Often the argument is presented in terms of means and ends. Paul Ramsey, in his book, The Patient as Person (15), repeatedly refers to consent as being the only mechanism through which experimental subjects can be treated as more than mere means. For him as for most others who have written on the ethics of clinical research, consent serves the role of preserving the status of the subject as a person.

Perhaps the clearest and most concise presentation of consent as the legal and moral touchstone of clinical research is found in the major codes and declarations that give this subject its historical perspective. The most strongly stated is the first section of the Nuremberg Code (1947):

> 1. The voluntary consent of the human subject is absolutely essential. This means that the person involved has legal capacity to give consent; should be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision (3, p.73).

In the Declaration of Helsinki's Recommendations Guiding Doctors in Clinical Research (adopted by the World Health Organization in 1964), we find the following in section III. "Non-therapeutic Clinical Research":

> 3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured (4, p.75).

And in the American Medical Associations Ethical Guidelines for Clinical Investigation (adopted in November 1966):

> 4. In clinical investigation primarily for the accumulation of scientific knowledge --
>
> C. Minors or mentally incompetent persons may be used

as subjects only if:

> i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.
> ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject (5 p.77).

I have quoted from these documents at length to illustrate the central importance of the consent doctrine, but also because I will make reference to these particular sections later in this discussion.

Paul Ramsey has presented what is widely accepted as the clearest statement of the ethics of non-therapeutic research on children. In his analysis, which I referred to above, consent is the key ethical concept. In presenting Ramsey's position, I will quote at some length from his major work, The Patient as Person, both to illustrate his argument and because the paper I have chosen to critically analyze, namely that by McCormick, is an attempt to question the ethical argument presented by Ramsey.

Ramsey's presentation is clear and almost brutally harsh. It was received by the pediatric research community as the proverbial "cold slap in the face." It is hard to overstate the effect that this book has had on those engaged in clinical research in pediatrics. He begins with the Nuremberg statement (quoted above) and his intention is clear from the outset. He presents consent as a "canon of loyalty expressive of the faithfulness-claims of persons in medical care and investigation" (15 p.10). "An informed consent alone exhibits and establishes medical practice and investigation as a voluntary association of free men in a common cause" (a partnership as opposed to a contract) (15 p.11).

From this bulwark principle, Ramsey then turns to a discussion of research involving children or incompetents.

> From consent as a canon of loyalty in medical practice it follows that children, who cannot give a mature and informed consent, or adult incompetents, should not be made the subjects of medical experimentation unless, other remedies having failed to relieve their grave illness, it is reasonable to believe that the administration of a drug as yet untested or insufficiently tested on human beings, or the performance of an untried operation, may further the patient's own recovery [direct medical benefit] (15 p.11-12).

Ramsey does leave open the question of what constitutes "benefit" and states that it must be interpreted as "whatever is believed to be of help to the child" (15 p.12), but then clearly rules out any non-therapeutic experimentation: "Where there is no possible relation to the child's recovery, a child is not to be made a mere object in medical experimentation" (15 p.12). As an indication of Ramsey's reaction to any such research we need only read a few lines down: "To experiment on children in ways that are not related to them as patients is already a sanitized form of barbarism."

Clearly no one involved in clinical experimentation would disagree with Ramsey on the question of consent. However, they had always accepted the proxy consent of the parents or legal guardian of the child as adequate (see A.M.A. guidelines above). Ramsey's reaction to the notion of proxy consent is harsh and clear: "The attempt to consent for a child to be made an experimental subject is to treat him as not a child. It is to treat him as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research. If the grounds for this are alleged to be the presumptive or implied consent of the child, that must simply be characterized as a violent and false presumption"

(15 p.14). Ramsey explains that consent, "true consent", requires freedom to choose and ability to know. To enter into the research partnership requires the act of a "true volunteer" and the notion of volunteering another is totally morally unacceptable.

Ramsey backs down from this position only once to allow for medical investigation on children in "face of epidemic conditions endangering also each individual child" (15 p.16). But, this obviously provided little comfort to the pediatric research community.

The last possible "safe ground" for the research community is Ramsey's next target. Curran, Beecher and a host of those involved in pediatric research had argued that proxy consent was not ruled out in experimentation on children where there was "no discernible risk" (1,2). (We will examine this position below). Ross G. Mitchell had even defined what was meant by "no risk" and argued that experiments on children or incompetents could be "permissible provided that the risk does not exceed the ordinary risks of daily living" (14). But even in this later catagory, Ramsey remains firm. To involve a child in non-therapeutic research regardless of risk is to treat him as a "means only." The issue for Ramsey is the "wrong of making a human being an object and using him in trials not in his behalf as a subject" (15 p.36). To back up his position he turns to a legal distinction and points out that the law clearly recognizes "harmful invasions of the body" (leading, if consent has not been obtained, to medical negligence) and "unconsented touching." In one case the suject is "harmfully used" and in the second, "used with no harm." Ramsey quotes Reubhausen to clarify: "What is involved is the right of each of us to determine for ourselves not alone the extent to which we will share ourselves with others, but the timing and the nature of any such sharing" (15 p.34 ff, 43). Thus, for Ramsey, "no consent rather than no risk or no discernible risk is the decisive point . . ." (15 p.39).

In summary, Ramsey allows those involved in pediatric research some latitude in determining possible benefit (as in N.I.H category 3.), but clearly rules out any experimentation in category 4., except under epidemic conditions. The reason Ramsey's argument has been so devastating to the research community is that he has taken the cornerstone of medical ethics, namely consent, and argued from it to his conclusion ruling out non-therapeutic research on children. His argument is clear and , to many, compelling.

It is difficult, if not impossible, to find a more clear ethical discussion on this subject. Virtually every other major ethicist leaves the question either undiscussed or unanswered. Most other discussions, particularly those in the medical literature, begin with a lengthy and lamenting discussion of the need for such experimentation and then proceed quickly to a legal or quasi-legal discussion of guidelines or procedures that should govern such research. Henry K. Beecher in several articles on the subject proceeds in this fashion. In "Scarce Resources and Medical Advancement" Beecher briefly discusses the English Common Law interpretation, a strict reading of which would make non=therapeutic research on children illegal; then, the "silence" of American law. He then moves to set down a tenable proposal to govern such research. The central theme of his proposed policy is that proxy consent is necessary in all cases and "sufficient when no discernible risk in involved and the safety and value of the proposed study are supported by the investigators' peers" (1 p.76). "The issues are: 1) no risk, if below the age of understanding (which Beecher does not define, but implies would be 14 or 16 years of age); 2) screening and approval of a review board; 3) purposeful useful goals; 4) no coercion or deception of the parents, but their full understanding and consent" (1 p.77-8).

Curran and Beecher in a widely quoted article, "Experimentation in Children" discuss the legal and quasi-moral issues involved (2). The significant issue introdued into the legal (and ethical) discussion by this article is the issue of benefit. The authors review Bonner vs Moran (2 Ref.9) a case involving a 15 year old who served as a skin graft donor to his cousin without explicit parental consent; and, a series of cases in Massachusetts involving kidney donation by identical twins to sibling twins (2 Ref. 10,11). Obviously, neither case deals directly with the question of non-therapeutic research, but they form the basis on which a claim can be made that "benefit" can be derived by a child involved in non-therapeutic research as long as discernible risk is absent. However, the authors fail to define the concept of benefit.

Curran and Beecher interpret the English Common law view as "silent" on the subject of non-therapeutic research which carries no risk of harm to the subject. They proceed to propose "standards for investigation involving children." We will examine the two that are relevant to our subject:

> 2. Where the research is not therapeutic in nature subjects who are minors may be included in the investigation if the minor is 14 years of age or older and is found after interview by the research team to be intelligent enough and mature enough to understand the nature of the experiment . . . its purposes . . . and the hazards . . . and given his consent thereto. In addition . . . the informed consent of parents is also required in such situations only where there are discernible risks or hazards beyond simple inconvenience.

> 4. There should be strong reasons in professsional judgment for the use of immature children (those under 14 years of age) in any clinical investigation where there is no direct benefit intended for the child. However, such involvement should not be ruled out as illegal or unethical in all circumstances. Such involvement should be allowed where the study has firm medical support and justification, promises new knowledge of benefit to science and to mankind, and where there is no discernible risk for the child subject (2 p.81) .

This proposed policy would then represent a compromise from Ramsey's position. It would allow research in N.I.H. category 4. on children where there is "no discernible risk." This position has been widely accepted by the research community; however, clearly this would impose significant limitations on pediatric research. Most studies would involve some risk even if extremely small and remote. It is also widely recognized that since the law has been silent on this issue, this proposal represents a tentative legal position at best and obviously has been given no firm ethical basis.

The effort to fill the legal vacuum and avoid the radical ethical stance as proposed by Ramsey has led to a careful re-examination of the various codes and declarations on which much of traditional medical ethics in the area of human experimentation is based (3,4,5). Although the Nuremberg code seems to rule out any non-therapeutic research on those incapable of giving informed consent (see above), most authors have insisted that it is necessary to take into account the environment and circumstances that gave rise to the code, namely the Nazi trials. Clearly the code can be interpreted as silent on this issue (see Curran and Beecher) or as a clear condemnation of such research (Ramsey).

The Helsinki Declaration has been interpreted by most authors as accepting the validity of proxy consent (see above).

The A.M.A. guidelines accept the notion of proxy consent, but limit its acceptability (see above). However, there have been widely differing interpretations of what is meant by "suitable" (section C.i.) and different opinions on whether "an informed and prudent adult would reasonably be expected to volunteer" his child if any risk were involved in the investigation (section C.ii). This test of reciprocity is seen by many as important and valuable, but by few as definitive.

The situation at present is confusing to say the least. The mechanism by which most recent authors and investigators have sought to cope with this problem is to dispose of guidelines and to rely instead on the mechanism proposed by the N.I.H., namely a variety of multidisciplinary committees to provide review, supervision and protection of children involved in research. A recent article in the Journal of Pediatrics by Lowe, Alexander, and Mishkin is an example of this approach (12). The authors accept the proposal by Robert Marston (of the N.I.H.) for research projects which are to involve children (8). The proposal calls for a central (federal) Ethical Review Board to be maintained at the N.I.H. and a Protection Committee at the institutional site (in addition to peer review committees previously required by N.I.H.). The former should attempt to "determine ethical propriety and community acceptability" of a proposed project. The latter would "assess the adequacy and reasonableness of parental consent and the consent of the child subject when the child was over six years of age. In addition it would supervise recruitment of subjects and provide a representative without bias to whom either the child or parents may go to discuss questions . . . (12 p.472). The authors admit that the proposal does not solve either legal or ethical dilemmas and even increased the complexity of undertaking research on children. However, it has the advantage of some flexibility, does not limit research to "no risk" experiments, and allows the research community to continue to function in spite of the lack of clear guidelines. In another effort to shed light on the problem, the congress has recently passed legislation establishing a "National Commission for the Protectionof Human Subjects of Biomedical and Behavioral Research." It is yet unclear what position such a commission will take on our topic and what guidelines or procedures it will call for. It is also felt that a pending revision of N.I.H. guidelines for studies involving children may help to provide direction.

I would like now to turn to a discussion of Richard McCormick's essay. This paper represents a serious attempt to deal directly with the ethical questions involved in proxy consent. It also is an attempt to critically examine Ramsey's position. Although one should be wary after reading the first several lines of this paper and finding the statement that the author considers such experimentation "utterly essential," I think the essay is provocative.

After a review of the unclear legal and medical opinions on the subject, McCormick turns to a discussion of Ramsey's position. He agrees with Ramsey that "consent is the heart of the matter." However, he does not feel that Ramsey has adequately answered the question: "Why is their (the parents) consent considered null here (non-therapeutic experimentation) while it is accepted when procedures are therapeutic? To say that the child would be treated as an object (Ramsey) does not answer this question (13 p.9).

McCormick then proceeds to "unpack" the notion of parental cons . Parental consent for therapy is morally valid "precisely insofar as it is a reasonable presumption of the child's wishes." Why would the child so wish? According to McCormick, because he "ought to do so" (13 p.9). In order to explain, McCormick reviews what he refers to as the "natural law tradition" which "argues that there are certain identifiable values we ought to support, attempt to realize, and never directly suppress because they are definitive of our flourishing and well-being" (13 p.11). Proxy consent in a therapeutic setting is legitimate "because we know that life and health are goods for the child, that he would choose because he ought to choose the good of life, his own self-preservation . . ." (13 p.16). From this McCormick proceeds to argue that "a certain level of involvement in non-therapeutic experimentation is good for the child and therefore he ought to choose it" (13 p.12). He quickly points out that there are "limits beyond which sharing is not or might not be a good." "Whether a person ought to do such things is a highly individual affair and cannot be generalized in the way the good of self-preservation can be" (13 p.13). However, there is a level of experimentation, McCormick feels, that all "ought to want," not because it is for our good, but because in no real way is it harmful. What the child "ought to want" is involvement in experimentation that is: 1) "scientifically well designed (and therefore offer(s) hope of genuine benefit)"; 2) "cannot succeed unless children are used"; and, 3) "that contain no discernible risk or undue discomfort for the child" (13 p.14). McCormick replies to the obvious objection that he is making charitable acts obligatory by claiming that "there are some things that all of us, simply as members of the human community ought to do for others." For him these include any works that involve "no notable disadvantage to individuals yet offer genuine hope for general benefit" (13 p.16).

To those who would argue that this is a "slippery slope" (Ramsey), McCormick claims that there is a clear dividing line that is reached "when experiments involve discernible risk, undue discomfort, or inconvenience" (13 p.17). Not all children would be so obligated, and McCormick would leave out at least the institutionalized.

I feel that McCormick's argument is vulnerable to a number of serious objections. First, McCormick implies that children are what I would term morally transparent to their parents or guardians. By this I mean that parents and guardians have the capacity to know what the actual moral obligations of their children are. One of the major problems of the natural law position (and in particular many of the past Roman Catholic formulations of natural law) is that it assumes that by his reasoning abilities one can not only know his/her own personal moral obligations, but the actual moral obligations of others. The major addition of Western Protestant thought to this tradition has been what might be called a doctrine of humility or a doctrine of man's finitude. None of us are perfect or ideal moral judges even of our own actions and making judgments about the moral acts of others is highly problematic. Most contemporary moral philosophers would argue that human agents are neither transparent nor opaque, but some often frustrating mixture of both. A well-developed doctrine of consent is seen as an essential check or addendum to our limited powers as moral judges.

Second, McCormick implies that infants have moral obligations to the community and that infants can morally benefit by fulfilling these social obligations. He would have us treat infants as moral persons and as moral agents. It is impossible for me to accept that a being can be morally obligated or can benefit morally without some even very limited capacity to "see" or "understand" or be "aware" of moral obligations. The infant is not even capable of awareness of him/herself as a separate self much less a self with obligations to a wider community.

Third, McCormick is arguing that a certain level of involvement in non-therapeutic research is obligatory for all members of the human community. He implies that this level of involvement is not a charitable act or what might be called "second-mile" behavior. I am not inclined to agree with him on this point, but even if this is the case no one has the right to determine how, when and in what manner we will fulfill this obligation except in time of emergency or where some previous moral obligation exists. We have an obligation to help our neighbor-in-need, but our neighbor has no moral warrant to demand this help at a particular time unless, as in the case of Kitty Genovese or a drowning person, our neighbor is in dire need, we are there and capable of rendering the help needed and represent our neighbor's last resort. William E. May has expressed this criticism of McCormick in several articles on human experimentation in recent issues of the Linacre Quarterly. I would, except in times of emergency, find it difficult to justify compulsory blood donation programs for all healthy adult members of the community.

Fourth, McCormick implies that the "good" which is the result of clinical research, e.g., a cure for arthritis, is something that we owe future generations. I think we are clearly obligated to preserve this world for our children, but they have no moral warrant for expecting a world free of arthritis and we are under no moral obligation to free the world of it. Within the constraints of the moral nexus in which we exist we are free to try to learn all we can about this disease and to use that knowledge to respond more adequately to those who suffer from it and even to prevent its development. However, the result, should we develop the ability to "cure" or prevent the disease, will be a *gift* which we leave to our children *not* what is justly theirs.

Finally, McCormick fails to hear what is a central theme in Paul Ramsey's work. Ramsey demands that we treat patients and research subjects as persons. To treat another as a person demands that she/he be treated in such a manner that she/he will judge our intervention into her/his life to be morally justified. McCormick implies that to treat someone as a person demands that we do what is right for or to that person. *If* we were or had access to perfect moral judges and could know what the other ought to do or want in each and every situation, He would be right. However, this is *not* the case. I would argue that when parents give proxy consent they can only *assume* that what they are doing is right, they cannot know that the intervention is justified. I think McCormick is claiming that we can use infants on the basis of our moral presumption that they ought to consent to being used. We cannot know what the infant ought to choose. Since we cannot ask him/her this question, we must limited our interventions into their lives to those interventions undertaken in response to their needs or when their life, freedom or well-being is at stake. Even in this latter case, we must seriously consider not intervening when our intervention can be postponed until they can participate in the decision and where our intervention would render impossible the future enjoyment of a basic human right.

However, McCormick's essay does drive home our obligation as parents and other responders to the needs of children to seek a moral justification for all our interventions into their lives. McCormick has also led me to ask a question I feel Ramsey has not taken seriously. If the child will not benefit medically (either directly or indirectly) from involvement in non-therapeutic research, can he/she benefit in any other way? In particular, can children morally benefit from involvement in such research? I would claim that, it is possible for children (below the age of 14 years) to benefit morally from involvement in clinical research. If this is the case, it is possible for them to be involved as more than mere means (Ramsey).

Ramsey has clearly pointed out that the covenant of loyalty between parents and children demands that children be protected. This covenant clearly obligates parents to protect children from harm or even from "offensive touching." However, this is not the only demand placed on parents by this convenant. A vast literature on the moral development of children has clearly shown that the parents play a central position in this process. Parents are obligated to both govern and to enhance the moral development of their children. Most would agree that the primary mechanisms for this process are example and education. However, the recent work by Kohlberg and others had shown that actual experience in making moral decisions and actual exposure to situations in which there is an opportunity for moral growth are also important and may well be essential in this process. Parents are obligated to encourage their children to take advantage of these opportunities for moral growth. In order that children might become sensitive to moral obligations and develop a disposition toward choosing that which is good, they must experience situations in which that sensitivity is required and which enhance this disposition.

I would argue that involvement in "no risk" clinical research can be such an experience. I would not agree with McCormick that such involvement is usually obligatory or that it would always, or usually, be activity that would enhance moral sensitivity or a disposition towards the good. I would only claim that it is one of many activities from which parents might select to this end. I would also disagree with McCormick in that I would argue that such experiences can be of no moral benefit to infants or children prior to what is generally referred to as the age of reason (5 to 7 years). To have the purpose of furthering moral development, the experience would need to be one of which the child subject was aware and had general understanding.

It seems that this position would get us over the hurdle of Ramsey's principal objection, namely that children were being "used" as mere means. If the end or purpose of the involvement is the moral development of the child in addition to the end of obtaining knowledge, the child is involved as a means and as an end in her/himself.

In terms of Ramsey's second objection, namely that of confusing justice and love, we are able to respond that as parents we have no right to force our children to undertake non-obligatory "second-mile" behavior, but rather have an obligation to stimulate and encourage them to develop the obligatory disposition towards such behavior (see Dyck, "A unified theory of virtue and obligation"). One mechanism that we can use to this end is to become involved with our children in actual "second-mile" behavior. We are allowed to do this as long as such behavior does not make it impossible to fulfill other parental obligations, i.e. that to protect our children. Clearly, "no risk" clinical research is a candidate for such learning experience. I would also point out that many parents would disagree (and many children resent) Ramsey's claim that children are "not capable by nature or grace" of charitable acts.

It should be noted that I used the word "with" in my discussion of parent-child experience in clinical research. Wherever possible research protocols would be required that would allow for parent and child to participate in the experiment as "joint-subjects". Where this could not be done, direct parental involvement in a supervisory capacity would be mandatory.

In completing this argument, I would once again agree with Ramsey that such experiences can only be morally acceptable if the child is a willing participant. And our discussion ends where it began, namely with consent. Obviously, when we speak of the child-subject's consent we are not talking about the fully informed and totally free consent which would need to be provided by his/her parents. But, I would argue that no child should be allowed to participate in non-therapeutic research unless serious effort is made to obtain his/her consent. It would be a more adequate safeguard if this consent were obtained by an unbiased subject-representative in addition to that obtained by the research team and that provided by the parent.

In this situation, the role of the parent is central. The parent must determine whether or not such an experience might be of benefit to the child's moral development. The parent must also monitor and supervise the experience to determine that this end is being achieved.

The role of the research community is clear. Experiments must be proposed that are compatible with this goal of enhanced moral development. I would tentatively propose the following guidelines for the research community.

Guidelines for Non-therapeutic Clinical Research on Children Five to Fourteen Years*

(*Experiments in the N.I.H. Category 4.)

1) Meticulous experimental protocol subjected to institutional peer review.

2) Experiment would provide significant and essential new knowledge.

3) The knowledge to be gained by the experiment is such that it can only be obtained by experimentation involving children.

4) The experiment must involve no discernible risk or significant discomfort. (No greater risk or discomfort than would be encountered by the child in his family life (14).)

5) Where possible, the same or a similiar experiment must have been performed on adult subjects and been found to be without risk.

6) Informed parental consent mandatory. Parents must be involved as experimental subjects with their children where possible. Parental supervision would be mandatory where this was not possible.

7) The consent of the child subject must be obtained by a member of the research team and by an independent subject-representative.

8) Review by Ethical Review Board and review and supervision by an institutional Protection Committee (6). (Children in this age range must be included as members of the latter for review and supervision of experiments in this category.)

In summary, I would agree with Ramsey that to "use" another as a "means" is incompatible with moral behavior. I would agree that a subject who cannot experience, understand, and freely participate cannot be involved in non-therapeutic clinical research. However, I would argue that children in the age range of 5 to 14 years are able to participate with awareness and understanding in clinical research. I have argued that such involvement can be a source of enhanced moral development and should be allowed in "no discernible risk" experiments.

The guidelines I have proposed differ with those prepared by Curran and Beecher (2) and the N.I.H. (6) in several respects: 1) Where possible the same or similar prior experiment on adult volunteers would be required to establish more clearly its "no discernible risk" nature; 2) the consent of the child-subject would be required; 3) involvement of parents in the actual experiment and parental supervision where this is not possible are required; 4) involvement of children on the institutional site's Protection Committee; and, 5) a lower age limit is provided, tentatively 5 to 7 years.

I realize that to argue that children should be allowed to participate in non-therapeutic clinical research is to propose an argument that will be welcomed by an eager research community and that abuses are possible and will occur. However, I also realize that children are allowed by society and their parents to participate in many activities involving significant risk (e.g., competitive sports) which may or may not provide the opportunity for enhanced moral development I feel can result from children participating with their parents in high-quality, adequately reviewed and supervised clinical research.

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William G. Bartholome

PROXY CONSENT IN THE MEDICAL CONTEXT: THE INFANT AS PERSON

This paper is the attempt of a parent, pediatrician, and one concerned with the problems of medical ethics to examine critically or, as Richard McCormick has termed it, to "unpack" the notion of proxy consent. I am motivated to write this paper by the finding that discussions of proxy consent in the literature (7;11;21), with few exceptions, are "too clean", "too simple", "too tidy" to account for a large number of problem situations which I have encountered in my life as a father and as a pediatrician. I cannot promise the reader a systematic formulation or anything resembling a "complete theory" of proxy consent. My aim is primarily to muddy the waters, to point out ways in which accepted notions and concepts do not fit or fail to take account of the complexity of situations in which such consent is called for. I will argue that the accepted notions are inadequate primarily because they allow parents and others involved in the lives of infants and children a degree of comfort and assurance that is inappropriate to what is at stake in being a parent or in attempting to provide medical care to children. The accepted notions would have us believe that infants and children are "transparent", or "knowable" in ways that even our closest friends and associates are not. I will feel that this project is a success if I am able to point out the ways in which the accepted concepts are built on a fundamental error and what morally significant considerations are not included. What I am asking of parents, pediatricians, and others is to "see" and "feel" the difference between the statement: "I know my infant child would have me do "x" on his/her behalf" and the statement: "I assume my infant child would have me do "x" on his/her behalf."

Although proxy consent is a requirement for the provision of medical services to any "incompetent" person, I will limit my discussion to proxy consent for children. I do this both because my discussion will speak to these other cases by implication and because I am not sure that what is morally at stake is the same in the case of the infant and that of a "mentally incompetent" octogenarian. I would argue that the fact that the octogenarian has a "personal history" and the infant does not is a critical factor in attempting to justify proxy consent.

I will also not speak directly to the issue of proxy consent with regard to the human fetus for similar reasons. However, the reader may note that many of the claims that I will make have serious implications particularly in the area of fetal research. I would also argue that there is serious tension between a position that would argue that the fetus is a part of the woman's body and one which would hold that the infant is not the property of the parents.

In order to avoid the difficult problem of determining when a young person is able to give his/her "informed consent" to medical care, I have chosen as my "patient" the infant. Clearly this is an issue which any theory of informed consent must address, but I feel and will argue that the issue of proxy consent becomes less problematic, at least from a moral point of view, as the patient develops the capacity to make choices and to communicate these choices and their reasons to others. Many parents feel that decision-making on behalf of their children is least complicated when they are infants and most complicated when they are teenagers. I will claim and defend the position that this widely accepted "feeling" is not only wrong, but symptomatic of the inadequacy of popular conceptions of justifiable interventions into the lives of children. I think that in selecting the infant

I have selected the most difficult case.

One also finds in the recent literature on proxy consent in medicine a distinction between what are called "therapeutic" and "non-therapeutic" or experimental forms of medical intervention (7;14;16). I agree with these authors that this is an important issue to examine. However, I find as a pediatrician that no clear dividing line exists between these forms of intervention. I also find certain forms of intervention (e.g., genetic screening) that seem to fit in neither category. My concern is with an issue that is prior to this distinction: How do we as parents and pediatricians justify any medical intervention into the lives of our children and patients?

Finally, I will not discuss in any detail what may seem at first sight to be an irrelevant question, namely: how do we justify interventions into the lives of animals? This question is important because the accepted notion of proxy consent fails to adequately account for our intuitive feeling that the justification of an intervention into the life of a human infant should somehow differ from our justification of an intervention into the life of a pet. Do we "owe" our infants more than "humane" treatment? Do they have a right to more? I will argue that one of the central questions to be raised and answered is: Is the human infant a member of the human community, a person?

CASES

I elected to include a section on cases for the purpose of forcing the reader to think about the notion of proxy consent "at the front line," in situations in which a decision must be made. I want to present the reader with situations in which acceptance of the traditional concepts do not seem to fit. If the cases make the reader uncomfortable, they achieve the intended end. I feel that it is necessary to present these cases in order to prepare the reader to "hear" my argument. In order to avoid the charge of artificiality, I have chosen "real" cases, i.e., cases that are recorded in the medical literature or with which I have been confronted as a pediatrician.

Case 1.

Mrs. W is the 42 yr. old mother of six children. She is now pregnant. At the time of conception, Mrs. W. and her husband were using contraceptives and both consider the pregnancy "unplanned." However, both agree not to proceed to abortion. During her first visit to her obstetrician late in the third month of her pregnancy, Mrs. W. is told by her physician that she is at significant risk (1 in 30) of having a child with Down's syndrome or "mongolism." She is also told that a procedure has been developed for screening her pregnancy for this abnormality (amniocentesis). Mrs. W. informs her physician that she will discuss the matter with her husband. He reminds her that she is already beginning the second trimester of her pregnancy and that the decision must be made as soon as possible. After extensive discussions with her husband, friends, family and local pastor, Mrs. W. returns six weeks later requesting the procedure. Her physician is extremely reluctant to perform the procedure. By his estimate Mrs. W. is now 22 or 24 weeks into her pregnancy. After a prolonged discussion of risks and the like, he agrees to proceed. However, when he introduces the needle into her uterus to aspirate some of the amniotic fluid for the test, Mrs. W. begins to have uterine contractions. In spite of medication to stop labor, the contractions continue and one hour later Mrs. W. delivers a fetus (infant) estimated to be 26 to 28 wks. of gestational age. She has many of the clinical signs of Down's Syndrome. Mrs. W. demands that the fetus (infant) not be sent to the premature nursery, but rather be kept in the delivery room (assuming that without a supportive environment the fetus/infant would die). The obstetrician elects to respect her demand since he had agreed to provide abortion services if the test had been positive for Down's Syndrome. Two hours later the fetus/infant is still breathing (although with difficulty) and has a pulse of 120/minute. The delivery room nurse calls for the pediatrician.

Case 2.

Mrs. B. had her right breast removed for cancer in 1973 at the age of 32. Because of her age and a suggestive family history an extensive analysis was undertaken of the incidence of breast cancer in her family. It was discovered that her grandmother, her mother, two of her mother's three sisters and her own sister (age 37) had had cancer of the breast. It was felt that she and her family had a genetic predisposition to the development of this tumor. She elected to have her opposite breast removed in 1974. This breast showed evidence of microscopic tumor development. Her younger sister, age 23, had her breasts removed that same year. Study of her breast tissue revealed no evidence of tumor. However, in late 1974, Mrs. B.'s 15 yr/old daughter was found to have cancer of the breast and had both breasts removed. In Feb 1975 Mrs. B. gave birth to a girl. As a result of the influence of maternal hormones, the breasts are completely deliniated at birth and it is possible to remove all breast tissue. It seemed possible to do what would be a major surgical procedure under local anesthesia, save the infant the risk of developing breast cancer, and allow her to avoid the serious psychological trauma of the possibility of having to have her breasts removed after puberty. Mrs. B. gave her consent to the operation.

Case 3.

Tay-Sachs Disease is a recessive genetic disease, i.e., both parents must be carriers of the gene and there is a 1 in 4 risk of having children with the disease. The disease is a fatal disease marked by rapid deterioration of the brain beginning in the first year of life with death occuring usually by age three. Methods have been developed for both detecting the carrier state and for making the diagnosis in the fetus. Since the disease is primarily confined to Jewish people of Eastern European heritage, it is possible by screening this population to identify all carriers, "at risk" couples, and to monitor all the pregnancies of the "at-risk" couples. Mrs. R. and her husband are both carriers of the disease. Their second child was affected and died at 26 months of age. Their first child is a 4 yr. old girl who is not affected but has a 1 in 2 chance of being a carrier. Her parents bring her to the screening center requesting that she be screened for the carrier state. They argue that if she is identified as a carrier they will encourage her as she grows up to date non-Jewish men; and, to marry a non-Jew or at least ask any young Jewish man with whom she is becoming "emotionally involved" to be screened for the carrier state.

Case 4.

Mr. and Mrs. R. have just had an infant son. The child is healthy and the examination is unremarkable except for the presence of severe talipes-equino-varus deformity of both feet ("clubfoot" deformity). An orthopedic specialist is consulted and strongly recommends immediate casting to begin treatment and to prevent the necessity of multiple extensive surgeries at a later date. She points out to the family that late surgical treatment often fails and that intervention in infancy is essential if the child is to walk normally. Mr. R. tells the physician that he cannot stand the thought of his son having to wear casts on his legs for the first six months of his life. He claims that to torture the baby in this manner is inhumane and he will not permit it. His wife agrees. The hospital lawyer is consulted and tells the physician that since the intervention is not life saving and since correction can at least be attempted (in spite of poor chances of success) at a later date that the parent's refusal to give consent should be respected.

Case 5.

Mr. and Mrs. S. have a 6 week old girl with a large capillary-cavernous hemangioma of the face. ("Strawberry birthmark") They bring the infant to a plastic surgeon and request that the lesion be removed surgically or treated with radiation. The surgeon explains that radiation treatment would lead to extensive facial scarring and that it would be impossible to remove the lesion surgically without permanently disfiguring her face. He explains that a high percentage of such lesions regress spontaneously without significant scarring and that some respond to treatment with drugs given for a prolonged period of time. He recommends that they wait and offers to follow the infant for the problem. However, the parents claim that they cannot stand the way people look at their daughter and that they have trouble looking at her. They state that they "can't" wait any longer even if it means risking permanent scars. They argue that she can have plastic surgery later in life to remove any scars or remedy any disfigurement. The surgeon, sensing their determination and worried that any surgeon who would operate on the infant would likely be less competent, agrees to do the surgery.

Case 6.

After an extensive analysis and a ten year study of neonatal circumcision, the American Academy of Pediatrics in 1971 issued a position paper which points out that there is no medical justification for routine circumcision of the newborn infant. The Academy strongly urges all members to point out this finding to parents. Three pediatricians who make up the pediatric staff at a small community hospital decide that they will no longer provide this service to newborn infants unless there is a demonstrable medical need. The obstetrical staff at the hospital agrees and the policy is made public. Mrs. J. gives birth to a male infant. Although she had been given a copy of the policy statement on admission, she claims to have the right to determine if her son is to be circumcized or not. She also claims that since the hospital is the only one in the area which provides obstetrical and nursery care they must do the procedure. Her lawyer discusses the situation with the legal representative of the hospital and the pediatrician is ordered by the hospital director to do the procedure or lose her privileges at the hospital.

Case 7.

Mr. and Mrs. Y bring their 18 month old daughter to an ear, nose and throat specialist because of "problems with ear infections." After obtaining a history and records from the child's pediatrician it is determined that the child has had a total of two ear infections since birth. The specialist explains to the parents that this is not a significant problem and that surgery is not indicated. The parents explain that their oldest child developed meningitis with an ear infection at 19 months of age and died. They are afraid that their second child might do likewise. They ask the physician to remove her adenoids and place ventilating tubes in the ears to prevent their daughter from developing infections. The doctor explains that the procedure does not prevent infections, but only makes them less likely in certain patients. He explains to them that their second child is not at an increased risk of meningitis and that the contemplated surgery involves small but real and known risks to the life and health of the child. The parents insist. They argue that they understand the risks; that their fear may be without scientific basis; but, that they want the procedure performed.

Case 8.

Mr. and Mrs. L are informed that their infant son has been found on a routine 6 week check up to have an inguinal hernia. They are informed of the significance of this finding and the risks. It is recommended that the hernia be repaired as soon as possible. However, the father claims that as an infant he had a similar problem and never had surgery. Examination of the father reveals a massive inguinal hernia. The parents claim that if the baby has any problem with the hernia they will have it repaired. Reluctantly the pediatrician gives in to their wishes. Two weeks later the infant was seen because of inguinal swelling, irritability, and vomiting. The surgeon is called to see the baby and tells the parents that the hernia sac contains parts of the infant's intestines that are "stuck." The parents ask if it can be "fixed" without operation and the surgeon reduces the content of the sac into the infant's abdomen. He explains that this will happen again and again until the hernia is surgically repaired and that each time it happens there is a risk that the intestine's blood supply will be cut off with serious complications to the infant. Again, the parents refuse to consent to the procedure. The surgeon demands that they sign a form stating that they took the baby home "against medical advice" and relieving him of responsibility. They do so and take the infant home.

Case 9.

Mr. and Mrs. C are approached by Dr. R who wants to study the effects of sensory deprivation on the human infant. The purpose of the study is to compare EEG tracings ("brain waves") of the 4 week old infant during sensory deprivation and those of adults. The study is to last 48 hours and is not felt to have any discernible risk. The infant is to be placed on a floatation mattress in a soundproof room, blindfolded, and fed by nasogastric tube. He is to be constantly monitored via closed circuit T.V. and other equipment and the parents are assured that the study would be discontinued immediately if any "problems" arise. The study has previously been reviewed by the hospital review committee and the human subjects committee. The parents give their consent.

Case 10.

At 4 weeks of age, Infant B.J. was diagnosed as having Turner's Syndrome. This abnormality of the chromosomes is characterized by short stature, failure of normal ovarian development with subsequent failure to mature sexually and sterility, and mild learning disabilities. Patients are not mentally retarded. This patient also has coarctation of the aorta (narrowing of the main artery from the heart to the body) which is associated with the syndrome. At three months of age the infant develops intractible heart failure (heart failure that cannot be controlled by medical therapy). The parents are told that she will require surgery to correct the narrowing in the aorta. The risk of mortality with surgery is estimated to be 15 to 20% and essentially 100% without it. The parents decide that in view of the other problems which their daughter has the surgery should not be done and "nature" should be allowed to take its course. The surgeon after pleading with the parents for several weeks is unable to change their decision and the surgery is not performed. The infant died three weeks later. The surgeon's husband tells her: "You did all you could. They were confident that they had the infant's best interests at heart. They knew they were doing what she would have wanted. After all they are in a better position to know." The surgeon reminded him that the infant had been in her care longer than she had been home and said: "Neither they nor I were in a position to know that much about her."

It is my hope that I have sensitized the reader. I would ask that the reader attempt to use his/her power of imagination and stay in this tangle of claims and counter claims for the rest of the paper. In the concluding section of the paper, I will analyze these cases from the point of view of the infant as person.

I will now present a series of "claims." I believe that this series of claims can form the basis of policy guidelines for the provision of medical services to infants. The claims are based largely on what I believe is a more basic claim which will be defended in the remainder of this paper; namely, that infants are members of the human community and that this fact must be reflected in the treatment accorded them by parents, physicians and society at large.

GENERAL PRINCIPLES FOR POLICY DECISION-MAKING IN THE PROVISION OF MEDICAL SERVICES TO INFANTS

1. The proxy consent of parent(s), guardian or court must be obtained in order to morally justify a medical intervention on behalf of an infant. This strict moral requirement can be waived only in the event of an immediate and grave threat to the life or health of the infant in a situation in which the time necessary to obtain such consent would or would be likely to lead to severe, irreversible harm to the infant.

2. Although a necessary condition of the morality of any medical intervention [except in emergency situations as described] such consent is never a sufficient condition of the morality of the intervention.

3. When a medical intervention is considered and/or undertaken on behalf of an infant, the infant is the party whose "interests" are at stake, i.e. the infant is the patient. Clearly the fact that the infant exists as a part of a family must be taken into account as it should be when a medical intervention is considered or undertaken on behalf of an adult who is a member of a family.

4. Because the infant's ability to communicate his/her "interests" to parents, physicians, and society is essentially non-existent, it is more difficult to know what is actually morally right, wrong, good or bad for him/her than it is for an adult or even an older child. The infant is thus one of, if not the most, "morally opaque" members of the community. For the infant, moral justification of interventions must depend on assumptions based only on what is *prima facie* right, wrong, good, or bad.

5. Any medical intervention into the life of an infant for which there is no demonstrable need is *prima facie* wrong.

6. To undertake any medical intervention that can be delayed without significant irreversible consequences on the life or well-being of the infant until the infant has developed the capacity to share in the decision-making process is *prima facie* wrong.

7. Any medical intervention which would have as one of its consequences rendering impossible the future enjoyment of any fundamental human right is *prima facie* wrong.

8. The traditional distinction made between "ordinary" and "extraordinary" medical interventions is not applicable to the infant unless it can be established that the infant is: (a) dying, and (b) the intervention is likely only to prolong that process. Any medical intervention on behalf of an infant who is not dying and is: (a) undertaken in response to a demonstrable need; (b) cannot be delayed without irreversible consequences; (c) does not preclude the future enjoyment of a fundamental human right; (d) offers reasonable hope of success; and (e) can be provided to any infants with similar needs in an equitable manner by the delivery system is *prima facie* obligatory.

The principles outlined above may overlap and it may well be possible to formulate and to state them in more precise terms. However, my purpose is not to establish this list as true or to justify or support each claim or principle. My purpose is to demonstrate that some list of claims like these can be established from what I think is a prior claim or principle. I will argue that acceptance of this "higher-order" principle pushes one toward accepting this list or a very similar list as "second-order" principles which are to be utilized to establish policy or to guide one in attempting to justify a medical intervention (or non-intervention) into the life of an infant. I am not arguing that this list can be logically deduced from the higher-order claim, but that if one accepts the prior principle these principles, or ones that are similar can be defended.

THE INFANT AS PERSON

I have borrowed this heading and paper title from Paul Ramsey's *The Patient as Person* [19] primarily because I am very much indebted to him and his book which pointed me on the way to this argument. The most particular debt I owe to Ramsey is for what is both said and provocatively left unsaid in a footnote:

> To base "Good Samaritan" medical care upon the implied consent of automobile accident victims is quite a different matter. A well child, or a child suffering from an unrelated disease not being investigated, is not to be compared to an unconscious patient needing specific treatment. To imply the latter's "constructive" consent is not a violent presumption, it is a life-saving presumption, *though it is in some degree "false* [accent mine] [19:p.14].

Why would Ramsey claim that proxy consent to a life-saving medical intervention was "in some degree false"? What was he trying to say? Ramsey does not say. He leaves his reader with the question.

I don't think Ramsey used the right word for what he was trying to say; however, I have no single word to put in its place. What Ramsey is trying to tell us is that there is always something uncomfortable, unsettling, or "false" about giving consent for an intervention into the life of another human being; someone else's life and well-being are at stake yet we are asked to provide consent. I don't think that Ramsey realizes that his feeling that something is "false" about this situation is something that is felt on almost a daily basis by pediatricians and by other professionals who have infants and children as patients or clients. It is also a feeling that all parents have had at one time or another about interventions of their own into the lives of their children. That particular unsure, uncomfortable, uneasy feeling is a combination of doubt and what Schweitzer must have meant by reverence. We parents and professionals who deal with children get that feeling because we are aware of both who we are (with all our limitations) and who they are: dependent, vulnerable, and yet real persons.

The higher-order claim or principle for which I will argue in this paper is essentially Kant's claim. Yet I don't think even he was aware of how radical this claim was when applied to infants and children. I will argue that if one accepts this fundamental Kantian principle in order to apply it to the case of the infant in a society that accepts a pluriform concept of "the good" a list of seemingly radical and "unrealistic" second-order principles or policy guides is required.

This fundamental principle can be stated in a variety of ways. Kant's second formulation of the "categorical imperative" is: "Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end" (12:p.64). What Kant is saying is that a human being must always be treated as a human being. I think the claim can be stated in more contemporary language by claiming simply that we are all members of the same community: the infant is a member of the human community, a person. As a result of his/her membership in this community of beings-with-ends (if you prefer Kant's terminology) or persons the infant has a basic, inalienable, "natural" and "absolute" right which forms the basis of all prima facie human rights, e.g., life, liberty, etc. (The latter rights may also be basic, inalienable, and "natural" but are never absolute, i.e. they must always be taken into account; are right or wrong-making characteristics of actions.) I think it may well be possible to defend the position that the infant must have the same prima facie human rights as the adult, but I am not attempting to defend that position. I am attempting to defend the position that the infant has this more basic, absolute right on which a list of prima facie rights is or at least can be based. This right is simply the right to be treated as a member of the human community; the right to be treated as "more than" an animal or inanimate object. Both Rawls (20) and Morris (17) have called this "the right to be treated as a person."

The argument I will use to defend the claim that infants have this basic right is not a systematic position. I will present five arguments any of which I feel provide the outline of what is needed to defend this principle in a systematic way. I will present a brief version of each argument and point the reader to secondary material in which the arguments are carefully worked out in a detailed manner. I present five defenses in outline form rather than one systematic position both for the sake of brevity and for the purpose of demonstrating that it is possible to defend the principle in a variety of ways.

Before presenting arguments in support of this principle, I would like to point out that much recent talk about rights is so loose and conflicting that it is often difficult to know what is being talked about. Most recent writers have found it necessary to educate their readers in terms of what a right is. I will follow the terminology used by Feinberg (5), Morris (17), Hart (10) and McCloskey (15) and argue that a right is not a claim or a particular kind or form of claiming. It can form the basis of a claim or be claimed, but a right is most fundamentally an entitlement. And as all of these authors point out a right does not depend for its existence on the recognition of others. Often, as in this case, what is being claimed is that a person's right(s) be recognized. That is to say, that it should not be accepted as evidence against infant's right(s) that they are not given explicit recognition in this society. I am not saying that rights or talk about rights does not require a community or even a community with certain constituitive characteristics (see Golding: 8).

Secondly, an entitlement does not depend on its bearer or possessor having any relevant power or capacity: rights are distinct from powers. In fact one need not necessarily have the power or capacity to claim the right as theirs. Rights can be claimed in support of a third party. Thirdly, rights do not depend for their existence on the holder's knowledge, awareness or capacity to enjoy the right in question. If you fall asleep you may not be aware of your rights, you may not be able to enjoy them but you clearly don't lose them. If as a result of an accident or intoxication you may lose knowledge, awareness, enjoyment and even the capacity to claim rights, but you don't lose your rights. You may not enjoy your right to life if you are extremely depressed, but you don't lose it. To have rights or entitlements it is only necessary that a being be a member of a community of rights holding persons. If you are a member of a community of rights holding beings, you have those rights regardless of your knowledge, awareness, capacities, or powers in regard to them. You are not always morally justified in acting on the basis of a prima facie right, but such a right is always a right-making characteristic of your action and any appeal that you are not so justified must be based on appeal to another prima facie right or the prima facie rights of another. If you are a member of a community of persons holding these prima facie rights, you also have the absolute right to be treated as a person regardless of knowledge, awareness or capacities.

ARGUMENTS ON BEHALF OF THE RIGHT TO BE TREATED AS A PERSON

I. Infants have special rights. Special rights depend on the existence of at least one general right: the right to be treated as a person.

The first argument follows closely that made by H.L.A. Hart in "Are There Any Natural Rights?" (10). I would argue that infants must be recognized as having rights that are the correlative of certain kinds of obligations. Hart points out that "special rights" have many sources such as promises, various forms of special authorization, and both special and natural relationships. Although I would be willing to argue that a formal promise made to an infant was morally binding and that the infant could be said to have a right to what was promised, I will limit the discussion to rights which are generated by natural and special relationships.

I would argue that as a result of the natural relationship between parents and children that parents have moral obligations vis a vis infants, e.g., provide adequate food, shelter, etc., or to find others who will fulfill these parental obligations. I would argue, following Hart, that such obligations give rise to a right or entitlement of the infant against his/her parents to adequate food, shelter, etc.

Secondly, I would argue that when an infant is born into the care of a physician or brought to a physician for care that the physician (or someone to whom he has delegated the responsibility) is obligated to provide medical care to that infant. (Such an obligation to the infant is clearly recognized in the law of torts.) This moral obligation of the physician arising from this special relationship gives rise to a right of the infant against the physician to medical care.

I would argue, again following Hart, that these rights depend on the existence of what he calls general right(s). An infant cannot be held to have these legal/moral entitlements unless he/she has at least one more basic right. I would argue that, at a minimum, the infant must be recognized to have the right to be treated as a member of the human community, as a person. If a society recognizes that infants have these "special rights" it must also grant that infants have at least this one general right.

II. In order to develop as persons, infants and children must be treated as persons.

This argument is alluded to by Morris:

> Brought to our attention, if we ascribe them (children) the right (to be treated as a person) is the legitimacy of their complaint if they are not provided with opportunities and conditions assuring their full enjoyment of the right when they acquire all the characteristics of persons. More than this, all persons are charged with the sensitive task of not denying them the right to be a person and to be treated as a person by failing to provide the conditions for their becoming individuals ....There is an obligation imposed upon us all, unlike that we have with respect to animals, to respond to children in such a way as to maximize the chances of their becoming more developed persons (17:p.127-8).

However, one gets the feeling that Morris is pleading with the reader rather than trying to prove his case. This impression is made all the more vivid by his reference to infants and children as both persons and beings who will or are to become persons.

A much more powerful argument which parallels the above is made by Landenson (13) on behalf of the right to freedom of expression. His argument based on material derived from Dewey and the Dewian tradition in philosophy of education is that the development of personal autonomy is impossible without freedom of expression. My argument is that if the role of parents, if the end of parenting is the formation of highly developed persons, i.e. persons who are free, autonomous beings capable of reasoned choices, it is essential that infants and children be treated as persons. If an infant is not treated as a person, this process of development is in a fundamental way rendered impossible.

III. If members of society or persons they delegate desire to have the right to intervene on behalf of abused or neglected infants it must recognize their right to be treated as persons.

My third argument is more pragmatic, but for anyone interested or involved with the problem of child abuse and/or neglect it is a very real one. I would argue that in order to justify intervention on behalf of an abused or neglected infant it is necessary that infants be recognized to have rights against both their parents and against society. This is especially the case if society wants to designate certain persons or categories of persons as obligated to intervene. It is necessary to grant that infants are not "part of" their parents nor are they owned by or the property of their parents. We feel that we are not justified in intervening on behalf of an animal if its owner who feels that the animal is too old, or too sick or too much trouble (has bitten ten children in the area in the last two months) should be put to sleep. We believe that given some limitations on what is "humane" treatment, pets are the property of their owners. If a set of parents elected to put their child to sleep because he was "lame" or too much trouble (had bitten twenty children in the last week) we would argue not only that these parents were not fulfilling their obligations to treat their child "humanely" but that we had an obligation to intervene on behalf of the child, that the infant had a right, was entitled, to our intervention. If the owner of a dog deeply concerned with the problem of overpopulation by dogs in his area, elected to have his female puppy "fixed" we would argue that this was his right since it did not involve inhumane treatment. Some would even praise the owner for his "social responsibility." However, if this same man deeply concerned with the population problem elected to have his infant daughter "fixed" we would argue that he had no such right. In fact, we would argue that we or some delegated responsibility had a right to prevent him from so acting. I would argue that the basic factor justifying our intervention must be that the infant is a member of the human community and has a right to be treated as such. If infants were not members of the human community and had no right to be treated as such, such interventions would be much more difficult to defend.

IV. Infants have "interests" in how they are treated. Only beings that are persons or developing persons have interests. Infants are developing persons and must be treated as such.

My fourth argument is based on what at first sounds like a very legal term, namely "interests." Morris argues that infants possess the right to be treated as persons "as an individual might be said in the law of property to possess a future interest" (17:p.127). Smith argues that the only factors which are to be taken into account in decision making about defective newborns are the "interests" of the infant and the health care delivery system (22). Although Goldstein's provocative book Beyond the Best Interests of the Child clearly demonstrates how this argument can be used against children (9), I think that Goldstein and others who have discussed this issue miss an important aspect of what might be called the interests of the infant. H.J. McCloskey's definition of an interest is crucial. He argues that an interest is "that which is or ought to be of concern to the person/being." "Moral rights can be possessed by beings who can claim them, or by those who can have them claimed on their behalf by others and whose interests are violated or disregarded if the rights are not respected" (15:p.126).

I would argue that the infant has interests, e.g. it would make a difference to the infant when be became aware of himself if during his infancy his parents had elected to amputate his thumbs to prevent his thumbsucking. The infant/child now aware of his body could rightly claim: "You certainly didn't have my interests in mind when you amputated my thumbs!" Such a claim could also clearly have been made on his behalf when he was an infant. Such claims are made almost daily by family counsellors, by parents and even by mothers-in-law on behalf of their new grandsons or grandaughters. If it is granted that the infant has interests, i.e. has something at stake even though he/she is an infant, then we must grant that we are talking about a being who is a person or at least a developing person and that that being has a right to be treated as such. I would argue with McCloskey that "until it is clear (beyond doubt) that they (infants) can never really be said to have interests, we (must) treat them as if they do" (15:p.127). I have never seen an infant about whom such a claim could be made with any degree of certainty. Some would argue that his claim can be made, for example, about anencephalic infants (infants born with no cerebral cortex). I would only observe that such a claim is clearly implicit in the terminology widely used in both the medical and lay communities to describe such infants. They are called "monsters" in order to clearly rule them out of the human community and to distinguish them from infants with a variety of severe defects and diseases whom we include. This tension and its significance is clearly seen in the extremely heated debate over "mere words" in the abortion issue. To subtly refer to the "fetus" or the "products of conception" as a baby is often the most inflammatory that could be done. We have to be able to include or not include beings in the human community on this basic level. There is no in-between; you are either in or out and its damn important which you are!

V. Life, well-being and freedom have both instrumental value, i.e. value to or for others or society and intrinsic value, i.e. value to the individual. The intrinsic value of things like relief from physical suffering seems to be equal for all. Therefore, all ought to have an equal right to relief from physical pain. This argument can be generalized to include equality of intrinsic value and rights to life, well-being, and freedom. Alternately, we have no rational basis on which to compare intrinsic values quantitatively; therefore, equality of right. Language provides our only access to intrinsic value. (Infants have no capacity to communicate.) Therefore, knowledge of actual intrinsic value of life, well-being, and freedom for the infant is impossible. This limitation must be reflected in treatment.

My final argument is the most complicated of the five. It is also the most essential and "troubling" in terms of its implications in regard to treatment. The argument on which it is based is presented by Gregory Vlastos (26) and developed by Richard Wasserstrom (24). It has the advantage of having been challenged by a potent critic: Kai Nielsen (18). Vlastos does not apply his argument to the infant, but implies that he feels it can be done.

Vlastos begins by arguing that we seem to "acknowledge personal rights which are not proportioned to merit and could not be justified by merit. Their only justification could be the value which persons have simply because they are persons: the 'infinite value' or the 'sacredness' of their individuality, as it has often been called" (26:p.91). Vlastos proceeds to argue that this "individual human worth" can be understood to refer, at least primarily, to the individual's well-being and freedom. He argues that although the extrinsic or instrumental value of our individual well-being and freedom may differ markedly, the intrinsic value of our well-being and freedom must be seen as equal: "one man's freedom (and well-being) are as (intrinsically) valuable as any other's" (26:p. 93-94). For Vlastos, equal intrinsic worth translates into a necessity for equal prima facie rights to well-being and freedom.

Nielsen, in arguing that a "Master Morality" that would deny human rights except to an Ubermensch is just as defensible as a moral position as the position of equal natural rights, points out that when Vlastos won't allow for us to judge men simply as men that his argument is overpowered by "what Nietzsche would regard as the stench of Christian moralism" (18:p.586). He argues that Vlastos brings his Christian egalitarianism to his argument and does not derive it from the argument. However, in the footnote at the end of his essay, Nielsen seems to sense the power of Vlastos's argument. As Nielsen notes, the power of Vlastos's argument can be seen clearly in the case of something like the relief of acute physical pain. Aside from highly unusual cases, all humans seem to have an equal aversion to this form of suffering. That is to say, their intrinsic valuation of such an experience seems to be essentially identical. Since it seems possible to establish this fact, it is difficult to defend relieving the acute pain of one person rather than another except for some stringent moral reason. That is, they both have an equal prima facie right to the relief of the pain or to avoidance of the painful situation.

Nielsen seems to admit that it may be possible to establish such an argument for the case of relief of acute physical pain, but he doesn't think that gets one very far in defending a doctrine of equal human rights. Vlastos would argue that the same argument is applicable to each human right, or at least for the equal right to well-being and freedom. Wasserstrom develops the argument further. He does not claim that we could establish the truth of equal intrinsic value for all goods. His claim is that even though we don't know that intrinsic value is the same, we do know that "we have no meaningful or reliable criteria for comparing and weighing capabilities for enjoyment or for measuring their quantity or quality." If we know that we don't, "we probably know all we need to know to justify our refusal to attempt to grade the value of the enjoyment of these goods" (24:p.106). Nielsen wants to claim that we have a rational basis for differential treatment, namely "total value." He implies that we can sum the intrinsic and instrumental value of a man's freedom or well-being and thus have a basis for comparison of granting rights. But what Wasserstrom is trying to say is that we have no way of putting "intrinsic value of 'X' into the total value equation since we have no means of quantifying or measuring it." Wasserstrom's position is that if one is dealing with a commodity that can't be measured that the only reasonable assumption is an assumption of equity. It seems to me that this is the critical issue and needs to be heard. The reader will see what happens if we take this position seriously in applying it to the newborn.

Toward the end of his paper Wasserstrom seems to retreat from this strong position and argue that what is really involved is a choice. Are we to live in a society in which certain persons are systematically "read out of the human race" or not? The assumption of equal intrinsic worth of human well-being and freedom is basic to the survival of our society. Nielsen agrees, but then points out that such an argument does not provide the grounds "for believing that such rights ought to be both respected and acknowledged" (18:p.594).

But what both Vlastos and Wasserstrom are trying to do is highly significant. By asking us to focus our attention on a realm of value which many philosophers refuse to admit even exists, they are challenging us to defend a position which makes most morally sensitive people uncomfortable. If we would disagree with these authors we are forced to say that either there is no such thing as intrinsic value of our well-being or freedom or provide some mechanism by which such value can be quantified for the sake of comparison. We are forced to provide some mechanism for saying A's life or freedom is more or less valuable to A than B's life or freedom is to B. Most of us would be willing to say that, at least intuitively, that kind of operation appears impossible. Comparing what my life means to me with what your life means to you seems, at least on the surface, to be trying to compare us in ways that destroy the fact that we are individuals. I would argue that the only way I could come to know anything about what your life means to you is through communicating with you over a long period of time (years). If you told me that you didn't value your life or didn't value it as much as you did, for example, vanilla ice cream, my reaction would be to say that I didn't know you well enough to "know what you really meant by that claim." I would argue that to claim that I can know how much you value your life, your well-being, or your freedom, I would have to claim that I knew you as well as you knew yourself. If one adds any doctrine or theory of the unconscious, it must be admitted that we are even somewhat "opaque" or less than completely knowable even to ourselves. To claim that kind of knowledge about another human being (with the possible exception of "life-long" friends or perhaps a spouse of some 50 years) is to this author the ultimate in human hubris.

If it is granted that another "adult" member of the human community is opaque to us to this degree in terms of the intrinsic value of life, well-being, or freedom, is not a member with whom we cannot even communicate in any morally significant way even more "opaque"? Who is to claim to know how valuable an infant's life or well-being is to him/her? The infant is not even aware of his/her existence as a valuing self! His/her life and well-being are valuable to him/her yet the infant is not even aware of this fact. To claim to know that an individual infant will not value his/her life or not value it highly is to pretend to have access to a crystal ball. Anyone who would make such a claim is claiming access to knowledge or feelings that do not yet exist!

It might be objected: "But you are claiming to know that the infant will value his/her life, well-being, and freedom then it becomes possible to do so!" I reply that I know no such thing. I live in a world where the most down-trodden, the most crippled, the most "miserable" of my fellow creatures place a value on their lives that staggers those of us who are the fortunate ones. We often find it impossible to understand why these people do not put an end to their "miserable" existences. Yet those who do take this "bold" step seem to come predominantly from the ranks of those of us who "have it made." I make an assumption, nothing more, nothing less. But my assumption has built into it something that those who would claim access to such knowledge does not. My assumption is open to challenge by the central actor in the drama. I allow my assumption to be subject to the review of my most astute critic, the infant on behalf of whose life, well-being or liberty I have intervened.

Once again the critic will object: "Once he/she becomes aware of his/her life, his/her existence as a valuing self, he/she is no longer free. By prolonging life, by your intervention you place him/her in a position where it is no longer possible to elect non-existence. Few of us are so strong; to choose death, for a knowing self, is to have to choose self-annihilation!" I can only ask my critic at this point to make that claim to any member of our society who has had to "fight" for life, well-being, or freedom. Tell them that the only reason they don't end their meaningless lives is that they are trapped by their knowledge of themselves; tell them they are too weak to do what is the "reasonable".thing to do!

In summary, I have presented five arguments in support of my claim that infants have an absolute, inalienable right to be treated as a member of the human community, i.e. as a person. We must now ask: "What does that mean?" "What content can we give to this very 'formal' claim?"

APPLICATION OF THE RIGHT TO BE TREATED AS A PERSON TO THE INFANT

In an extremely provocative article on proxy consent Richard McCormick confronts Paul Ramsey on the issue of the validity of proxy consent to the involvement of children in non-therapeutic research (16). The central issue is that of what it means to be treated as a person. McCormick asks Ramsey: "Why is their (parents) consent considered null here (non-therapeutic research) while it is accepted when procedures are therapeutic?" (16:p.9). McCormick claims that Ramsey has not adequately "unpacked" the notion of proxy consent. McCormick argues that "parental consent is morally legitimate where therapy on the child is involved precisely because we know that life and health are goods for the child, that he would choose them because he ought (is morally obligated) to choose the good of life, his own self-preservation as long as this life (that of the infant) remains, all things considered, a human good" (16:p.12). McCormick proceeds to argue that children, including infants, ought to want to participate in non-therapeutic clinical research that offers hope of genuine benefit and involves no "discernible risk or undue discomfort for the child" (16:p.14).

I think McCormick's argument that children, especially infants, have moral obligations to the human community is highly problematic, e.g. how can an infant have a moral obligation to do or be anything when he/she is not even aware of his/her existence as a self? However, McCormick is arguing that infants are moral persons, i.e. that any intervention into the life of an infant or child requires a moral justification. I would claim that McCormick has provided us with part of the content of the right to be treated as a person. The right to be treated as a person requires that any intervention, e.g. a medical intervention, must be justified morally.

However, McCormick's argument makes this author extremely uncomfortable. The unspoken claim "behind" McCormick's argument is that infants and children are what I would term morally transparent to, at least, their parents. In the case of infants and children we, or at least their parents, can identify the actual (as opposed to prima facie) obligations and duties: What is actually morally right/wrong, good/bad for that infant or child to do or be. Ramsey finds this not only strange, but dangerous and I agree. He would claim that even in the case of proxy consent for therapeutic interventions the consent is in some sense "false." Why? Ramsey believes that one of the fundamental reasons why consent is essential to the practice of medicine is that none of us is or has access to a perfect moral judge. Ramsey would argue that when we intervene in the life of another human being we are armed *only* with our *assumptions* about what that person would want or would feel was morally justifiable. For Ramsey to treat an infant as a person requires that we be aware of the fact that we are interfering in the life of another human being based on an imperfect knowledge of what is actually right/wrong, good/bad for that person. We have access to no better knowledge. Ramsey is no ethical relativist at this point, but clearly a doctrine of humility or human imperfection or finitude plays a major role in his approach to medical ethics.

John Rawls has argued that to treat a human being as a person demands that he be treated in ways that he can see as justifiable. He allows us to act on behalf of others, but asks that such interventions be guided by "the individual's own settled preferences and interests in so far as they are not irrational, or failing a knowledge of these by the theory of primary goods. As we know less and less about a person, we act for him as we would act for ourselves *from the standpoint of the original position* (i.e. with the veil of ignorance!). We try to get for him the things he presumably wants whatever else he wants. We *must* be able to argue that *with the development* or the recovery of his rational powers the individual in question *will* accept our decision on his behalf and *agree* with us that we did the best thing for him" (accent mine) (20:p.249). I am much more comfortable with Rawls' argument, but I am concerned that his "theory of primary goods" (which he calls a "thin" theory) can be used to render other human beings morally transparent in which case it is as "thick" as McCormick's claim that parents have perfect knowledge of their infants and children as moral persons.

What is missing? I would argue that what is missing is what could be termed an adequate doctrine of inviolability. I have argued that infants are more morally opaque than adults. Rawls would agree. But Ramsey (and a host of others who have approached medical ethics from what has been called a "religious" position) wants to claim that human beings are in some sense inviolable. What is he trying to say? What is his concern? I think William May comes closest to discovering what Ramsey is trying to say in an article that he wrote in response to Richard McCormick (14). May argues that the most appropriate principle in ethics for the situation of medical intervention into the lives of infants and children is that developed by Simon, Powers and Gunnemann, namely the "Kew Gardens Principle." This principle was developed in the attempt to find a method of dealing with the case of Kitty Genovese in the Kew Gardens Section of Queens who was killed as scores of people looked on. The principle has four elements: "need, proximity, capability, and last resort" (14:p.249). If one approaches the issue of proxy consent from the framework of this principle, the key element is that of "need." Parents or their delegates clearly fulfill the criteria of "proximity, capability (along with the physician), and are often the "last resort." Intervention, in order to be justifiable must be in response to the fact that "some human good (life itself, health, justice) is being destroyed or imperiled in another human being" (14:p.249). May points out that a medical intervention into the life of the infant where no "need" existed for such intervention is thus prima facie wrong. One of the key ingredients, then, in justifying proxy consent in the medical context is necessity. "The ultimate reason why this is justifiable lies in the obligation incumbent on parents and others to care for children and other human beings who stand in need of help (accent mine)(14:p.250).

I have argued that the right to be treated as a person includes at least three major considerations or questions: (1) Can it be argued that this particular intervention is just or morally justifiable? (2) Am I as certain as I can possibly be that this particular infant will be able to see my action on his/her behalf as just or morally justifiable? And, (3) Is my intervention in response to a demonstrable significant need of the infant's and is my intervention such that it cannot be delayed without significant risk to the life, well-being, or freedom of the infant? I would argue that any intervention must answer at least all three questions affirmatively in order to constitute treating the infant as a person.

I would like the reader to now look again at the cases which I presented in the first section of the paper. I would like to present what I would consider application of our claim that infants have a right to be treated as persons to each case. I do not claim that my way of applying the principle is "right," but I would claim that using this principle does "push" one in the direction I outline in seeking "resolution" of these cases.

Case 1.

I would argue that Mrs. W's claim to a right to determine the fate of her liveborn fetus (or premature infant) is groundless. The infant is no longer her property (if it ever was) and should have been sent to the nursery at the moment of birth. He/she has a right to be treated as a person. Persons don't get sent to the morgue before they are pronounced dead. I would argue that the right to be treated as a person would have at least obligated us to provide her/him with an isolette. Once in the nursery, if it was felt that he/she was dying and that no intervention, such as respiratory therapy, could do more than prolong that process, just the provision of the isolette may have been the only form of justifiable intervention into his/her life.

Case 2.

Mrs. B's daughter was clearly at risk of developing cancer of the breast after puberty. Her mother's wanting to save her the trauma of having her breasts removed is clearly admirable, but the procedure could have been delayed for at least 15 years without significant risk to the child and she could have shared in this admittedly difficult decision.

Case 3.

Mr. and Mrs. R have demonstrated no significant "need to know" if their daughter is a carrier of the disease. Their daughter is clearly in no need of this information at age 4. She may elect to have the test done at any time. Clearly since what is involved is her decisions about marriage and reproduction the decision should be hers.

Case 4.

Mrs. R's infant has a clear need. His parent's refusal to give consent to the intervention may well result in his being crippled for life. The physician is clearly obligated to take whatever legal steps are necessary to see that this need is met. If the issue is not one of legal negligence (I think most courts would argue that it was) it is at least serious moral negligence of the infant as person.

Case 5.

Mr. and Mrs. S are willing to expose their daughter to significant risk of permanent facial deformity to avoid the feeling they get when people look at their daughter in a certain way. The infant is not even aware of "the way people look at her." This intervention seems clearly not justifiable from a moral point of view and the surgeon's "lesser of two evils" approach is suspect.

Case 6.

The circumcision is clearly not in response to a demonstrable medical need. It also can clearly be delayed with no significant risk to the infant. (That the risks of the surgery would be higher for the older child is a factor he can take into account when he makes his decision about his foreskin.) Mrs. J's claim to a right to have her child's foreskin removed appears groundless.

Case 7.

Mr. and Mrs. Y's fear of meningitis in their 10 month old daughter is groundless. Yes, they do have the child's interests at heart, but the "interests" they see involved are no more than their own groundless fears, not what are, at least more probably, the interests of the child.

Case 8.

As in Case 4. Mr. and Mrs. L's son has a demonstrable medical need. The difference is in the risk to the child and the time frame in which intervention is necessary. Here the intervention can be delayed (at least for a period of weeks or months) while effort is made to help the parents see and understand the necessity for the procedure. I would set at least some time span, but would not ask for legal assistance immediately.

Case 9.

Aside from the fact that it could be claimed that this study was immoral because it promised no new or significant important knowledge, the infant is clearly in no need of this particular form of intervention. The question of whether he will agree with his parents that at that time he had a moral obligation to society to participate is one that at least is not clear. I would agree with Ramsey that in such a situation, the infant is not being treated as a person, but used as a means only.

Case 10.

This case seems to be one in which the parents could be said to have had the "best interests of the child at heart." It is also an excellent example of how dangerous that concept can be to infants and children. The parents decided that their daughter would have a strong negative interest in her life because of her handicaps. Yet, they provide no evidence for this claim. What would count as evidence? The crucial piece of evidence is unobtainable. I would argue that one must assume that the child would value her life despite the handicaps and be open to being found wrong by the child at a later date.

I have argued that the accepted doctrine of proxy consent must be refined. I have presented a series of problem cases in order to make the reader sensitive to these deficiencies. I presented what I argued was adequate (or at least promising) grounds for establishing a policy for newborn medical care. I argued that a list of principles such as these could be defended if it was granted that infants had a basic, absolute human right, namely the right to be treated as a person. I have pointed to five arguments as fertile ground to be examined to find support of this right and what seems to be three necessary (but not necessarily sufficient) conditions for its application to the case of the infant.

I do not claim to have presented a systematic formulation of a doctrine or theory of proxy consent. My purpose was to provoke thinking about the status of the infant in the medical care context.

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THE COMPETENCE AND FREEDOM OF CHILDREN TO MAKE CHOICES REGARDING PARTICIPATION IN BIOMEDICAL AND BEHAVIORAL RESEARCH

Lucy Rau Ferguson

THE COMPETENCE AND FREEDOM OF CHILDREN TO MAKE CHOICES REGARDING PARTICIPATION IN BIOMEDICAL AND BEHAVIORAL RESEARCH

Submitted to the National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research

Lucy Rau Ferguson, Ph.D.
Michigan State University

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In exploring this issue, I will take as basic assumptions a number of principles, most of which have been ably developed in the Commission staff paper on the use of children and the mentally disabled as research subjects (October 3, 1975).

First, the child is a person. This implies that she/he is not a chattel of his parents, of the state or of any other institution of the society, but has rights as an individual to respect, to privacy, to legal protection and to consideration as a valuable member of society. Also implied is a reasonable balance between the various views of the child as vulnerable and dependent and as a rational and moral being.

The second principle is that of self-determination. This requires "that each individual be given the opportunity to make an informed and uncoerced choice regarding participation in research activities". Consideration of the extent to which such choices can truly be informed and uncoerced for children will form the major substance of this report. The requirement of consent by parents or legal guardians to children's participation in research is intended to safeguard those whose capacity for self-determination is not yet fully developed or is temporarily or permanently impaired. As proposed DHEW guidelines specify, parental consent should be a necessary but not a sufficient condition for children's participation. Investigators should conduct research so as not only to respect but to enhance the child's developing capacity for informed choice.

The third premise is that the generation of knowledge and the discovery of scientific truth, whether or not the findings have immediate relevance to human welfare, is in itself a good. This implies that participation in research which meets acceptable criteria for scientific merit, provided the subject's basic human rights and welfare are not infringed upon, is desirable. This is a principle which we would hope that all responsible adults in our society would accept and which might legitimately form part of the system of values governing the socialization of our children. Given the strength of anti-intellectual forces within our society, however, one cannot necessarily take assent to this premise for granted.

Given these premises, the following issues related to seeking children's participation in research will be discussed in some detail:

I. What constitutes informed consent for a child? In seeking a child's participation in a study, how much interaction should she/he be given about the project and what will be involved for her/him? Should deception ever be used with children?

II. Proposed DHEW guidelines specify that no child of "sufficient understanding should participate in a non-beneficial research activity without his or her consent (or assent)". (Staff report, p. 6) The issue here is how to assess "sufficient understanding". The criteria to be proposed derive from our current knowledge of the general course of cognitive development. No specific "age of understanding" would seem generally appropriate.

III. Special problems of invasion of privacy arise from the type of "naturalistic" observational research very frequent in studies of the social development of young children. This problem as it applies to general issues of informed consent is dealt with to some extent in the report by Robert J. Levine (December 1, 1975). However, a number of speical considerations arise since certain research problems make it necessary to observe the ongoing flow of interactions among a group of children without their being aware of the presence of an observer, since awareness of the observer might well distort the very phenomena under study. Video-taping and other permanent recordings also present special problems in research to children.

IV. Another set of issues has to do with the incentives which are offered to children in seeking their ooperation in research. It will be proposed that:

A. Concrete rewards for participation, while they may very appropriately used under many circumstances, should never be of such high value to a particular child as to outweigh legitimate sources of reluctance. Refusal to participate in a research activity should never result in a child being deprived of material resources which he needs or legitimately expects to receive.

B. Undue social pressures should never be used to secure a child's cooperation in research. Such pressures include coercion by parents, teachers or other adult authorities, and manipulation by the investigator of peer group influences. Investigators should be aware of the subtle as well as the more obvious ways in which such social pressures can operate.

C. Appeals to the child's altruism, as long as they do not involve undue social pressure, are legitimate and may even contribute in constructive ways to the child's social development. It is important in this connection to understand something of the process through which motivation for pro-social behavior develops.

D. The most legitimate incentive of all for involving a child in research activities is the appeal to her/his intrinsic motivation to gain knowledge and understanding, her/his curiosity or "explorarory drive". It follows that participation in research should be a genuine and positive learning experience for the child, and that research involving children should conform to the very best standards of scientific excellence. Such research should never be incompetent or trivial.

V. Finally, since observance of the above principles is in practice impossible to legislate, it is of the utmost importance that research with children be carried out by those adequately trained and/or supervised. The background of the investigator in work with children, and her/his practical knowledge of child behavior and development, will be of crucial significance in determining the extent to which she/he is prepared to respect and enhance the freedom of choice of child subjects. Not all biomedical and behavioral scientists, though they may be highly competent in other respects, will be so qualified.

The membership of the Division on Developmental Psychology of the American Psychological Association and of the Society for Research in Child Development, two groups of behavioral and biomedical scientists primarily involved in research with children, have been very much concerned with the special ethical problems posed by research with child subjects. Both groups have developed very similar sets of ethical standards for the guidance of their membership. These are reproduced for the information of the Commission in Appendix A. What is said in this report is in general conformity with these standards, and with what I take to be generally accepted practice among my colleagues. It does go beyond them in a few specific points (e.g. the use of deception); these elaborations represent strongly held personal opinions of my own, and not necessarily the consensus of other developmental psychologists.

I. Informed Consent

Levine (1975) lists the following eleven elements of information which must be present in order to satisfy the requirements of informed consent.

1. Statement of overall purpose
2. Defining the role of the subject
3. Informing the prospective subject why he has been selected
4. A fair explanation of the procedures, including the setting, the time involved, with whom the subject will interact
5. Description of discomforts and risks
6. Description of benefits
7. Disclosure of alternatives
8. Offer to answer questions
9. Offer of consultation
10. Non-coercive disclaimer
11. Consent to incomplete disclosure

All of these elements seem relevant to research with child subjects, but some of them require special elaboration of their application to this population. In what follows, we are assuming that the investigator is dealing with a preschool-age or older child whose comprehension and verbal capacities are sufficiently developed so that she/he can understnnd explanations and questions which are put in simple, straightforward terms appropriate to her/his level of cognitive development. (The next section of this report treats in more detail the matter of differential capacities for understanding, and thus for consent, at different stages of cognitive development.) Particularly for the infant and pre-verbal child, where the parent or guardian necessarily acts as the child's surrogate in the consent process, the same considerations apply. All of the above elements should be included in communications to parents seeking their permission for their children to participate in research. Much behavioral research with infants and very young children in fact requires the presence of the mother, so that she is involved in the actual research procedures, and has the opportunity to ask questions and make choices about her child's participation at each stage of the proceedings.

Social science research often involves the element of consent to incomplete disclosure, since knowledge of the purpose of the study might well influence the behavior being observed. Under these circumstances it is customary to promise parents a more complete statement of purpose after the procedures have been completed, and eventual feedback of the findings. It is very important that investigators fulfill such promises (sometimes a problem when completion of data collection and analysis requires a long period of time, and either investigator of subjects may move in the meantime). It is also important that parents be given a genuine opportunity to reach the investigator, by phone or in person, and ask any questions or impart any reactions they may have to the study.

In order to preserve confidentiality, and since tests or other research procedures are generally experimentally in nature, it is accepted practice to provide parents with a general statement of findings but not with information about their particular child's "score" or performance. This should be made clear to parents in the beginning, since they will often volunteer their children as subjects with unrealistic expectations of what they may learn from the study or of benefits which may accrue from participation.

If, on the other ahnd, an investigator with clinical training identifies in the course of the research children who have specific symptoms of, e.g., severe behavior problems, medical illness or anomaly, cognitive defects, which may not have been previously identified, she/he has a responsibility so to inform the parents and help them to obtain appropriate diagnostic and therapeutic services. This is often a delicate matter, and requires extreme tact and skill in communicating with the parents, so that the professional responsibilities of the investigator, the welfare of the child and the autonomy and privacy of the parents are all adequately taken into account.

Some samples of letters to parents seeking permission for their children to participate in research are appended for illustrative purposes (see Appendix B.)

Considerable care must often be taken in making clear to child subjects that they have a genuine choice about participation in a research activity (element #2). In a later section we will deal with some of the subtler forms of coercion or social pressure which may be applied to induce children to cooperate in research. Often research is conducted in settings, such as school, where many other activities are required of the child and his freedom of choice is customarily limited. Thus the investigator must be at some pains to make it clear that this particular activity is truly voluntary, and that even if the child agrees initially to participate, he is free to change his mind and back out at any later stage of the proceedings. Even though the investigator may have provided what he considers an adequate description of what will be involved, the child may not fully comprehend the explanation or anticipate the consequences of involvement until he is actually in the situation, and then develops "cold feet". If this occurs, the child should be reassured that he is free to withdraw without incurring any negative consequences. On the other hand, an initially fearful, suspicious or reluctant child may be reassured by being given more complete information, by being allowed to view the actual experimental setting, by being allowed to observe another child participating if this is appropriate to the particular research problem, or by having his questions dealt with seriously and honestly.

Children will often have unrealistic fantasies as to why they were selected for a particular study, or it may be inadvisable to give them a full explanation of why they were selected (element #3). The latter may be the case when an explanation would bias the child's response to the research procedures, or might cause worry or reduced self-esteem (e.g. if a child is selected for the study because he has been identified as deviant in some way by his teacher, or because of performance on a test which has some socially undesirable connotations). Under such circumstances it is important for the investigator to be as honest with the child as possible about the nature of the research, criteria for selection, etc., without including potentially damaging information. In case the child has unrealistic fantasies, or suspects that he has been selected for reasons other than those provided, it is very important that he be invited and encouraged to ask questions and that these questions be dealt with sympathetically and straightforwardly. Particularly with young children, this will require skill and experience on the part of the researcher. Children will often have been discouraged from asking questions in the past, or had their concerns dealt with as being of no importance. It is very easy to convey or reinforce such messages to the child non-verbally; e.g. the researcher may ask him if he has any questions but then not give him adequate time to articulate them or respond hurriedly or superficially. In exploring the child's initial expectations or concerns about the research, and in the "debriefing" following his participation, the investigator should be able to empathize with the child's point of view and convey his respect for it.

Informed consent, according to Levine, involves a fair explanation of exactly what will be involved for the subject in participating, and an honest statement of any attendant discomforts or risks. It is often tempting to minimize discomforts involved in biomedical research or difficulties or frustrations which may be encountered in behavioral experiments in order to secure the child's cooperation. While there is no point in arousing unrealistic concerns or anxieties, it is only fair to the child to make clear to him exactly what will be involved. He will wish to know how long the procedures will take, any other activities they may interfere with, where they will be conducted and by whom. If the experimenter is a stranger to the child, it is desirable that she/he be given the opportunity to meet her/him before actually committing her/himself to the research. A child who encounters discomfort or interference with her/his regular activities, which she/he has not been led to expect, will be justifiably resentful and much less inclined to trust or to cooperate with researchers on future occasions.

It is the position of this writer that deception is never justified in research with children, although incomplete disclosure may be necessary in some circumstances. It will be noted that the SRCD (see point #10, Appendix A2) takes a less drastic position on this issue. The problem of deception in social psychological research has been thoughtfully explored by Velman (1967). It has frequently been found convenient in the past, in studies of conformity or altruism, or in order to manipulate such motives as need for achievement, to lead the subjects to suppose that their responsss in the experimental situation will have consequences for themselves or others which will not in fact ensue. The subjects are then disabused of the deception in a "debriefing" at the end of the session. While many interesting and important studies have been carried out in this way, many behavioral scientists have moved towards the position, particularly where research with child subjects is concerned, that such studies are unethical and liable to produce long-term social consequences so negative as to outweigh the benefit to be derived from their findings, even when they produce data which are clearly significant, both socially and scientifically. Greater ingenuity on the part of investigators may be required to discover natural conditions or alternative experimental manipulations which will permit investigation of the same processes for which studies using deception have proved convenient. This seems a worthwhile objective, however. Even when a child is disabused, in a post-experimental debriefing, of the belief the experimenter has originally created that a "stooge" is in acute distress or that the child's performance on a "test" will have academic consequences, she/he is left with the impression that investigators frequently lie to children, or lead them to expect things which prove not to be the case, and are not to be trusted. Thus the usefulness of such experimental manipulations is rapidly destroyed for any future occasions, and prejudices the subjects' willingness to believe what they are told in other studies, even if it is quite truthful. Such manipulations are counterproductive of the optimal condition for research participation, namely that it be an open and mutually informative collaborative enterprise between investigator and subject.

Levine also indicates (element #6) that there should be a clear statement of any inducements to be offered the subject for participating and that (element #10) it should be made clear to the subject that he is free to refuse to participate or to withdraw at any time, and that "such refusal or withdrawal will in no way adversely prejudice his future interactions . . . with the investigator". These are particualrly important points in studies involving children, and will be elaborated upon below in the section on inducements to be used with children for research participation.

To summarize what has been said in this section, children whose participation is sought in research activities should be given as accurate and as complete information as is consonant with their level of understanding. For all children who have developed beyond infancy and the preverbal toddler stage, and certainly for adolescents, parental informed consent should be a necessary but not a sufficient condition of their participation in research. Their own informed consent should be sought, they should be allowed genuine freedom to refuse to participate, and investigators in describing their research procedures should provide evidence that these conditions have been fulfilled.

II. "Sufficient Understanding"

If one considers the entire age span, from birth to the attainment of legal adult status at age 18 (or whatever is the local statutory provision), obviously a tremendous range of varying capacities for understanding is involved. So specific statement of a chronological age criterion for "sufficient understanding" (e.g. age 12, as specified by the British Medical Research Council) will be truly satisfactory since a given child's capacity to understand what is involved in a given research situation will vary greatly with her/his individual rate of development and with the complexity of the research problem or procedures. At the risk, however, of seeming to imply arbitrary cut-off points in what is always a continuous and individually varying process of cognitive growth, it seems convenient to discuss the separate considerations which apply to four different developmental groups: (1) infants and pre-verbal toddlers, (2) preschool and beginning school-age children (generally those below the age of 7), (3) pre-adolescent children and (4) adolescents.

A. Infants and toddlers

At this early stage of development, it is obviously unreasonable to expect the infant or very young child to make informed judgments about participation in research. Thus informed parental consent should be both the necessary and the sufficient criterion for the child's participation in any research activity which is deemed both non-therapeutic and nonharmful to the subjects. As has already been discussed in the preceding section, all of the criteria for truly informed consent should apply to the investigator's communications with parents both before and after the child's participation in research. Parents of infants are generally pleased to have them involved in research, providing there are no health hazards and that the investigator is helpful in solving the logistical problems often involved in bringing babies to a research laboratory. Mothers will often perceive such participation as an opportunity to learn something about their children's development, and investigators should take pains to see that the experience is a pleasant and informative one for the mother. Most investigators who work regularly with infants are indeed sensitive to these issues.

B. Pre-school and primary-age children

Children at these ages have some capacity for understanding verbal explanations and some ability to communicate their own questions and concerns to the investigator. Generally receptive language develops ahead of expressive language, and the child may understand considerably more than she/he is able to articulate. On the other hand, thought at these ages is generally "pre-operational", in Piagetian terminology. The child will understand explanations which are stated in concrete terms, have reference to the immediate situation and to her/his own recent experiences and in which the consequences to her/himself are made clear. She/he will have little capacity to understand abstract principles or issues stated from a point of view different from her/his own. Within these limitations of cognitive development, however, the investigator should provide the child with explicit information about what participation in the research involves for her/him, and some general statement about the purpose of the research (e.g., "We want to find out more about how children play, how they solve these problems, what they think about these questions", etc.). It is often appropriate to emphasize to the child that the investigator needs her/his help in this work, or game, or whatever, and the young child to whom one has appealed in this way and whose curiosity has been aroused will generally be eager to be involved. Research with young children generally requires skill in relating to them and sensitivity to their concerns and ways of thinking and expressing themselves. This kind of expertise derives from appropriate experience and training. Not all scientists necessarily work well with young children, so that some evidence of such experience or training is relevant in assessing a research proposal which involves young children as subjects.

Where investigators take care to establish appropriate conditions of rapport with their child subjects (this usually involves some previous period of establishing familiarity as well as an appropriate introduction of the specific research procedures), the children will generally be eager to participate in the research. To maintain their motivation, procedures should be planned so as to be interesting and pleasant for them. However, some important and useful research is intrinsically dull or frustrating for the young child, and it then may be appropriate to provide extrinsic rewards. Sometimes a child will balk at participation despite every effort to make it interesting and rewarding for her/him. Although her/his reasons for refusal may appear completely capricious or mysterious to the investigator, it will generally be neither feasible nor ethical to insist that the child continue. As anyone who has conducted behavioral research with two- or three-year-old subjects is well aware, they are quite capable of asserting their autonomy as far as cooperation in research is concerned. Their lack of consent may not appear particularly informed, from the point of view of the investigator, but one must nevertheless respect their choices. Obviously the ethical investigator is constrained from any form of coercion which would be harmful or seriously aversive to his child subjects. We shall deal with the specific issue of inducements to participate in more detail below.

C. The pre-adolescent (school-age) child

Much recent research on cognitive development, (see, e.g., review chapters by White, Stevenson, Berlyne, McNeill and Rohwer in Mussen, 1970) particularly carried out from the perspective of Piaget's theories, suggests that a number of critical shifts in cognitive capacities occur around the age of seven. At this point the child's perspective becomes less egocentric, she/he is able of conceiving a problem to some degree from the other person's perspective and understanding the consequences of her/his actions for others. The capacity for understanding simple scientific principles is evident, as well as capacity for social role-taking. The child is often willing to engage in altruistic or other pro-social forms of behavior, even at some cost to her/himself. She/he can make ethical or moral choices based on considerations beyond the immediate hedonistic consequences to her/himself. Thus both from a cognitive and a motivational point of view, considerable capacity for self-determination can said to be present in the school-age child. At this point her/his participation in research should clearly be based on essentially the same principles of informed consent that apply to adult subjects, and obtaining such informed consent from the child directly (including, if appropriate, having her/him sign a consent form) should supplement prior parental consent.

At this stage of development, while the child may not understand the abstract theoretical aspects of the research, she/he will be quite capable of understanding what is involved in most studies if the problem is stated to her/him in simple, direct, non-technical language. Investigators should never underestimate the understanding, the curiosity or the capacity for making informed choices of children at this age. If approached with honesty and respect, children will generally be pleased to cooperate.

Again it should be emphasized that the research should be made a genuinely informative experience for the child, one in which she/he is permitted to share in the scientific enterprise to the fullest extent possible. This will generally provide the optimum conditions of motivation. Many authors (e.g. Hunt, 1963; Berlyne, 1963) have pointed out the strength of curiosity or the "exploratory drive" as a motive for action. Beyond the immediate purposes of the specific study, participation in research which is an informative and positive experience for the child, can have the function of strengthening his own scientific curiosity, a potentially positive social outcome.

Since school-age children will often be asked to participate in research during school hours and in the school setting, care should be taken to differentiate the research from regular, required academic activities. Children will often be eager to cooperate if participating in research means "getting out of" class. If they will be required to make up work which they miss, this should be made clear to them. On the other hand, it should also be made clear that their performance in the experiment will have no direct academic consequences. Teachers can often influence children's attitudes towards participating in research in the way they introduce the investigator or the activity, and thus it is important to secure their understanding and willing cooperation. Teachers, obviously, should also be given some choice in whether their pupils participate in research in the light of their academic objectives. If class time is used for research, it is all the more important that this should be a genuine learning experience for all concerned.

D. The adolescent

While adolescents may not be accorded all the rights, privileges and responsibilities of adults in our legal system, as far as participation in nontherapeutic research is concerned, they should be treated by the investigator as adults. It is of course, necessary to obtain parental consent for the involvement in research of adolescents who are still legal minors, but this should always be supplemented by the equally informed consent of the subjects themselves. Teenage subjects should also be asked to sign whatever consent forms are used, and should never be required to participate if they are reluctant to sign. All the available evidence on cognitive development and the growth of intellectual abilities suggests that the adolescent's capacity for exerciseng independent judgment is limited, as compared to the adult's, only by a lack of relevant experience and information. If the researcher provides a clear explanation of the purpose of the study and what will be involved in participation, the normal adolescent should be perfectly capable of making an informed judgment. Furthermore, it will often be particularly important to the adolescent that his competence and autonomy be carefully respected. Adolescents are often deeply involved in the process of developing a sense of separate identity, and will be very resentful of parents or other adult authorities who make decisions for them. Many thoughtful young people are also deeply concerned with ethical issues, and will be very sensitive to the investigator's respect for their personal rights and dignity and appreciative of being treated as colleagues in the pursuit of knowledge. Adolescents generally react most favorably in situations in which they are given information which they feel is reliable and the opportunity to form their own judgments.

III. Invasion of Privacy

Much of the foregoing discussion of the informed consent process for child subjects implies the type of research in which the subject must actively participate in an experiment or a testing procedure, and thus can choose whether to cooperate or not. There are a number of types of study, however, in which such active participation and choice is not involved. These include "naturalistic" observational research, especially that involving concealed or "unobtrusive" observers; studies in which the subjects' behavior is video-taped or otherwise directly recorded and then later analyzed, perhaps in ways which the investigator did not originally anticipate; and studies in which data are not obtained directly from the subjects themselves, but rather from such secondary sources as school or health records.

A. The problems of confidentiality and invasion of privacy involved in the extensive accumulation, computerization, dissemination and scientific analysis of records accumulated on children in our society has been dealt with extensively elsewhere, particularly with reference to the results of psychological testing (see e.g., American Psychologist, 1965), and will not be discussed in detail here. Even if parental consent is obtained for using records for research purposes, the children involved are rarely informed or consulted. Where the records exist in any case, for other purposes related to education to education or health maintenance, and where adequate precautions are taken to preserve confidentaality in analyzing them for research purposes, no particular problems would seem to be involved. The question might at least be raised, however, as to whether children or adolescents ought to be informed and their permission sought for research uses which may be made of confidential records.

B. Naturalistic studies

A great deal of behavioral research, especially with young children, has sought to record the data of interest (e.g., linguistic responses, social interactions, play behaviors) under "natural" or ecologically representative conditions, free from the "artificiality" imposed by the experimental laboratory. Much of this research requires that the subjects be unaware of the presence of observers, on the assumption that such awareness might well distort the behavior of interest. Two general approaches have been taken to insure that the natural behavior of the subjects will not be distorted by their awareness of being observed: either concealing the observers by the use of one-way mirrors, closed-circuit TV monitors or other such devices, or having the observers visible but as unobtrusive as possible. Often the method of observation requires continuous recording, by means of note-taking, time-sample coding or the use of an event recorder. This record-keeping activity, if the observer is not concealed, is obvious to the child subjects and will often arouse their curiosity, The usual practice under such circumstances has been to introduce the observers to the children, with some simple factual explanation of their presence (e.g., "They are interested in learning more about how children play.") and allow the children to adapt to their presence so that they become a regularly accepted part of the social environment ("friendly furniture", as one investigator has phrased it) before formal recording of data begins. It is thus hoped that not too much distortion is introduced by the presence of the observers, although methodological questions can always be raised about the ecological validity of conclusions based solely on the behavior of children in such settings as university laboratory nursery schools. However, since parents are generally informed that such observations are part of the usual procedures in research nursery schools or other such settings when they enroll their children, and their permission is sought for specific studies, no problems of informed consent would seem to be involved.

Where devices such as TV monitors or one-way mirrors are used they will generally be noticed by the child subjects, who will often ask questions about them. It is generally good practice to explain their use to the children when they first enter the research environment, answer any questions factually, and give the children an opportunity to visit the observation booth, watch the monitor in operation or otherwise acquaint themselves with the observation devices in a direct and concrete way. If this is done, the children will at first be intrigued and excited, but once their curiosity has been satisfied, they will generally accept these devices as a natural part of the environment and cease to be particualrly concerned about them. Very occasionally a child will react with fear, embarrassment or unusual self-consciousness to the observation devices. If she/he cannot be readily reassured by factual explanations and demonstrations, her/his reaction should probably be discussed with the parents and the child allowed to withdraw from the situation. This would be a very unusual occurrence.

Where a permanent record is kept of such observations, especially by means of films or video-tapes where it is impossible effectively to conceal the identity of the subjects, permission should always be sought from both parents and children to retain such records, and the current as well as possible future research uses of the recordings explained. Consent from parents should be obtained in writing, and it is good practice to have children who are old enough sign the consent forms as well. Researchers often discover additional ways in which such recordings aan be analyzed, not related to the immediate purposes of the original study. Such possible additional usage should be allowed for in the original consent agreement; if the investigator promises to erase the recordings after a particular objective has been achieved, this promise should be conscientiously fulfilled. Occasionally a child will react with unusual self-consciousness or distrustfulness to being filmed or video-taped. Such a reaction would probably destroy the usefulness of the recording for the intended research purpose, so that if such a child cannot be readily reassured by the usual explanations of the recording procedures, she/he should probably be excused from the research for scientific as well as ethical reasons. As such recordings have come into general usage in research, behavioral scientists have generally become aware of the problems in rapport with subjects as well as the very great advantages they provide. Investigators are in general very much aware of the need to ensure the comfort of their subjects as well as to protect their right to privacy, and this forms an important part of the socialization of young researchers into the ethics of the profession.

In some types of "ecological" research, the observer is rendered unobtrusive by having another role in the situation (e.g., teacher, ward attendant, supermarket employee, librarian) and her/his role as researcher is not revealed to the subjects at all, at least until after the data have been collected. Often the use of such "unobtrusive" measures does not involve recording or even ascertaining the identity of individual subjects, and one could argue thet no invasion of privacy is involved. Should children under observation or their parents suspect that they are being watched, however, they might well react otherwise, and it would seem to be wiser and more ethical practice to explain to the "subjects" of such studies that their behavior has been recorded and to obtain their permission to use the data. Should this permission be refused, the investigator may well have lost time and effort (and perhaps even some representativeness in her/his data), but the subject's right to choose whether to participate in research will have been preserved. If investigators are generally honest, direct and courteous in their dealings with subjects, children as well as adults, the all-too-prevalent belief that scientists are "sneaky" and unconcerned with their subjects' feelings should be substantially weakened.

IV. Incentives for Participation

It seems almost too obvious to require specific statements that children should never be coerced into participating in research by the use of physical or psychological duress. However, there are a number of subtler forms of social pressure which should perhaps be discussed. Milgram's (1974) studies have impressively demonstrated how far adult subjects will be carried in violating their own humane principles by the need to conform to the instructions of an investigator whom they perceive as an authority. Children are likely to endow all adults with some degree of authority, and thus be even more strongly motivated to conform or at least to assume that cooperation is required of them unless it is made very explicit that they do have a choice. As we have indicated above, where research is carried on in schools or other settings where children are required to cooperate in many other activities, the investigator must make special efforts to make it clear that participation in research activities is voluntary.

If the investigator is someone of significance in the child's life (a teacher, parent, camp counselor, scout leader, etc.) it is particularly important to make clear that refusal to participate in the research will not prejudince the relationship (Levine's element #10 of informed consent). Such assurances may be difficult to make convincing to children in practice, and one might question the ethics of exploiting for research children who depend on the investigator in another role. However, some studies could only be carried out under conditions of close personal acquaintance and trust, and where no harm or serious discomfort is involved for the child, the scientific benefits to be derived surely justify the exploitation of the relationshpp, providing the investigator is honest with the child and strives to grant him as much autonomy as possible. Again it should be emphasized that most behavioral research is, or ought to be, a mutually informative and enjoyable activity for those involved.

Peer pressures can constitute an even more powerful source of of coercion than adult authority or love-withdrawal, especially for older children and adolescents, for whom acceptance by the peer group is a very important motive. Where an entire group of children or adolescents is participating in a study, the individual child who does not wish to be involved may find it difficult to make her/his wishes known, for fear of seeming deviant to the rest of the group. One form of protection which experimenters working in a school setting, for instance, can afford their subjects is to take all children whose parents have given their permission for them to participate to the experimental room, and then give each child an opportunity in private to choose whether she/he wishes to participate. If she/he refuses and simply returns to the classroom after an appropriate interval, it will not be obvious to the other children what that child's decision has been and her/his privacy and freedom of choice will have been protected. Not all research procedures make this possible, but there are other ways in which investigators who have some thought to the matter can protect children who do not choose to participate from adverse group reactions. Research procedures should always be planned so that if only some children in a group are selectdd as subjects, it should not appear to the others that they have been chosen for invidious reasons. Again, this may take some extra thought and planning, but seems worthwhile in order to avoid any semblance of coercion through group pressure or any undesirable social consequences for children who do participate. Where group testing procedures are involved, it may be worthwhile to have an entire group participate, even though the data from only some children will actually be used, in order to avoid adverse social effects. On the other hand, children may well be encouraged to participate in research if it is an activity shared by the group or if they hear from others that the procedures are fun or interesting. Such naturally occurring social incentives would seem to be quite legitimate, as long as they are not manipulated by experimenters to the detriment of the subjects or to secure cooperation which would otherwise be withheld.

Appeals to the child's altruism would also seem to be quite legitimate incentives. Recent research on the development of pro-social behavior (e.g., Rosenhan, 1972; Yarrow, Scott and Waxler, 1973) indicates that even quite young children will often behave altruistically, even at some cost to themselves, if it is clear that their actions will benefit others. Thus it may be legitimate to appeal to younger children on the basis that the investigator needs their help, or to older children by pointing out the ultimate social usefulness of the research. Cross cultural observations (see Whiting and Whiting, 1975) suggest that children who grew up in cultures where they are of necessity given considerable responsibility for care of younger siblings and other domentic tasks learn to behave in more socially responsible and less egoistic ways. Thus there may well be some benefits in the socialization process to be derived from giving children the opportunity to participate in socially useful activities, sucn as contributing to research.

It is customary in much behavioral and biomedical research, particularly if the research activity is not in itself particularly pleasant or interesting or involves some discomfort for the subjects, to offer them some modest tangible rewards for participation. Often the use of rewards of varying magnitudes or scheduled in various ways is in itself part of the research design. Small children maybe presented with small toys, trinkets, M&M candies or other such rewards. Older children may be given small sums of money or somewhat more elaborate toys, or the opportunity to earn special privileges. Such rewards, especially for less privileged children, may be important and quite legitimate incentives for research participation. Certain cautions sould be observed in their use, however. Material rewards should not be so overpoweringly large as to outweigh other legitimate sources of reluctance to participate. Manipulation of sources of reinforcement should not involve depriving a child of material benefits which he clearly needs or has a legitimate right to expect.

The most legitimate and appropriate incentive for participating in research, ultimately, should be the opportunity it affords the child to gain knowledge, satisfy his curiosity or share in an interesting experience. To the extent that researchers can make participating in studies an informative and intriguing experience for their child subjects, they will not only have secured their willing cooperation for the immediate occasion but also fostered the expectation that research activities and the generation of knowledge are rewarding as well as worthwhile experiences. This would appear to be a highly desirable long-term goal, from the point of view of the scientific community. In my own experience, children whose curiosity and motivation to be helpful are aroused in recruiting them as research subjects are almost invariably eager to participate and enjoy the experience. The children of developmental psychologists (including my own young son) are probably the most frequently used group of pilot subjects for colleagues' and students' research, and seem generally to be none the worse for the experience. It would be interesting to have more information about their reactions, gathered by disinterested parties.

V. Need for Empirical Data

This last point brings up one conclusion which has become clear to me in the process of working on this report, and which I believe deserves some emphasis. Although I did not undertake an exhaustive search of the literature on this point, I believe that there is in fact little information about children's beliefs and attitudes about participating in research or the effects on them of such participation. In the "debriefing" phase of an experiment, especially one which has involved only partial disclosure when subjects were recruited, the investigator generally tries to clarify the purposes of the study and supply more complete information about what has been involved from his point of view. However, only rarely are any data collected systematically about subjects' reactions to their own participation, any effects on their willingness to participate in future studies, what they thought of the research, etc. Where such information is collected, it is often primarily for the purpose of improving the research procedures or securing the subject's willingness to cooperate in a later state of the study.

Thus, nothing systematic is known about what it means to children, at varying stages of development, in varying population groups, under varying conditions, to participate in research or what the effects are on them of such participation. This suggests a very clear, specific need for empirical data in this area. Such data could be obtained in two ways: by undertaking some specific studies to explore children's thoughts, beliefs and reactions to research participation, and secondly by attempting to collect some systematic feedback on subjects' reactions from a large and representative series of studies, in many areas and using different methodologies, in which children serve as subjects. The latter approach would appear to require the lesser expenditure of funds and effort, and could yield quite meaningful information on the impact of various kinds of research experiences on the subjects.

Obviously, under the time constraints which the National Commission's present schedule of operations impose, it would not be possible to gather such data. It would be well worth considering, however, the possible usefulness and feasibility of undertaking such studies.

In the meantime, one can only reiterate the point made in the introduction to this essay. Most of what has been said here reflects the common practices and the published ethical standards of developmental psychologists and other responsible behavioral and biomedical scientists who work regularly with child subjects. Despite earnest and sincere efforts at self-regulation on the part of professional groups and widely published ethical standards, it is impossible to completely legislate ethical practices in research with children. Much must be left to the discretion and the sensitivity of the individual investigator. The professional credentials of the investigator, her/his level of training, or the adequacy of the supervision provided by more experienced investigators must serve as the guarantees of ethical practice. As we have said, impeccable scientific credentials do not necessarily guarantee familiarity with the needs of children, so that specific training and experience is necessary to guarantee that the investigator is adequately prepared thoroughly to protect the rights and welfare of her/his child subjects. Professional credentials and relevant experience, as well as specific descriptions of anticipated procedures, remain the best guarantee that participation in research will be a constructive experience for children.

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Appendix A,1.

Ethical standards for research with children. Reproduced from Newsletter, American Psychological Association, Division on Developmental Psychology, 1968, pp. 1-3:

Children as research subjects present problems for the investigator different from those of adult subjects. Our culture is marked by a tenderness of concern for the young. The young are viewed as more vulnerable to distress (even though evidence may suggest that they are actually more resilient in recovery from stress). Because the young have less knowledge and less experience, they also may be less able to evaluate what participation in research means. And, consent of the parent for the study of his child is the prerequisite to obtaining consent from the child. These characteristics outline the major differences between research with children and research with adults.

1. No matter how young the subject, he has rights that supersede the rights of the investigator of his behavior. In the conduct of his research the investigator measures each operation he proposes against this prinicple and is prepared to justify his decision.

2. The investigator uses no research operation that may harm the child either physically or psychologically. Psychological harm, to be sure, is difficult to define; nevertheless, its definition remains a responsibility of the investigator.

3. The informed consent of parents or of those legally designated to act *in loco parentis* is obtained, perferably in writing, Informed consent requires that the parent be given accurate information on the profession and institutional affiliation of the investigator, and on the purpose and operations of the research, albeit in layman's terms. The consent of parents is not solicited by any claims of benefit to the child. Not only is the right of parents to refuse consent respected, but parents must be given the opportunity to refuse.

4. The investigator does not coerce a child into participating in a study. The child has the right to refuse and he, too, should be given the opportunity to refuse.

5. When the investigator is in doubt about possible harmful effects of his efforts or when he decides that the nature of his research requires deception, he submits his plan to an _ad hoc_ group of his colleagues for review. It is the group's responsibility to suggest other feasible means of obtaining the information. Every psychologist has a responsibility to maintain not only his own ethical standards but also those of his colleagues.

6. The child's identity is concealed in written and verbal reports of the results, as well as in informal discussions with students and colleagues.

7. The investigator does not assume the role of diagnostician or counselor in reporting his observations to parents or those _in loc parentis._ He does not report test scores or information given by a child in confidence, although he recognizes a duty to report general findings by parents and others.

8. The investigator respects the ethical standards of those who act _in loco parentis_ (e.g., teachers, superintendents of institutions).

9. The same ethical standards apply to children who are control subjects, and to their parents, as to those who are experimental subjects. When the experimental treatment is believed to benefit the child, the investigator considers an alternative treatment for the control group instead of no treatment.

10. Payment in money, gifts, or services for the child's participation does not annul any of the above principles.

11. Teachers of developmental psychology present the ethical standards of conducting research on human beings to both their undergraduate and graduate students. Like the university committees on the use of human subjects, professors share responsibility for the study of children on their campuses.

12. Editors of psychological journals reporting investigations of children have certain repsonsibilities to the authors of studies they review; they provide space for the investigator to justify his procedures where necessary and to report the precautions he has taken. When the procedures seem questionable, editors ask for such information.

13. The division and its members have a continuing responsibility to question, amend, and revise the standards.

Appendix A,2.

Developmental Interest Group

Society for Research in Child Development

1975

Ethical Standards for Research with Children

Children as research subjects present ethical problems for the investigator different from those presented by adult subjects. Not only are children often viewed as more vulnerable to stress but, having less knowledge and experience, they are less able to evaluate what participation in research may mean. Consent of the parent for the study of his child, moreover, must be obtained in addition to the child's consent. These are some of the major differences between research with children and research with adults.

1. No matter how young the child, he has rights that supersede the rights of the investigator. The investigator should measure each operation he proposes in terms of the child's rights, and before proceeding he should obtain the approval of a committee of peers. Institutional peer review committees should be established in any setting where children are the subjects of the study.

2. The final responsibility to establish and maintain ethical practices in research remains with the individual investigator. He is also responsible for the ethical practices of collaborators, assistants, students, and employees, all of whom, however, incur parallel obligations.

3. Any deviation from the following principles demands that the investigator seek consultation on the ethical issues in order to protect the rights of the research participants.

4. The investigator should inform the child of all features of the research that may affect his willingness to participate and he should answer the child's questions in terms appropriate to the child's comprehension.

5. The investigator should respect the child's freedom to choose to participate in research or not, as well as to discontinue participation at any time. The greater the power of the investigator with respect to the participant, the greater is the obligation to protect the child's freedom.

6. The informed consent of parents or of those who act in loco parentis (e.g., teachers, superintendents of institutions) similarly should be obtained, preferably in writing. Informed consent requires that the parent or other responsible adult be told all features of the research that may affect his willingness to allow the child participate. This information should include the profession and institutional affiliation of the investigator. Not only should the right of the responsible adult to refuse consent be respected, but he should be given the opportunity to refuse without penalty.

7. The informed consent of any person whose interaction with the child is the subject of the study should also be obtained. As with the child and responsible adult, informed consent requires that the person be informed of all features of the research that may affect his willingness to participate; his questions should be answered; and he should be free to choose to participate or not, and to discontinue participation at any time.

8. From the beginning of each research investigation, there should be a clear agreement between the investigator and the research participant that defines the responsibilities of each. The investigator has the obligation to honor all promises and commitments of the agreement.

9. The investigator uses no research operation that may harm the child either physically or psychologically. Psychological harm, to be sure, is difficult to define; nevertheless, its definition remains the responsibility of the investigator. When the investigator is in doubt about the possible harmful effects of the research operations, he seeks consultation from others. When harm seems possible, he is obligated to find other means of obtaining the information or to abandon the research.

10. Although we accept the ethical ideal of full disclosure of information, a particular study may necessitate concealment or deception. Whenever concealment or deception is thought to be essential to the conduct of the study, the investigator should satisfy a committee of his peers that his judgment is correct. If concealment or deception is practiced, adequate measures should be taken after the study to ensure the participant's understanding of the reasons for the concealment or deception.

11. The investigator should keep in confidence all information obtained about research participants. The participant's identity should be concealed in written and verbal reports of the results, as well as in informal discussions with students and colleagues. When a possibility exists that others may gain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participants as a part of the procedure for obtaining informed consent.

12. To gain access to institutional records, the investigator should obtain permission from responsible individuals or authorities in charge of records. He should preserve the anonymity of the information and extract no information other than that for which permission was obtained. It is the investigator's responsibility to insure that these authorities do, in fact, have the confidence of the subject and that they bear some degree of responsibility in giving such permission.

13. Immediately after the data are collected, the investigator should clarify for the research participant any misconceptions that may have arisen. The investigator also recognizes a duty to report general findings to participants in terms appropriate to their understanding. Where scientific or humane values may justify withholding information, every effort should be made so that withholding the information has no damaging consequences for the participant.

14. Because the investigator's words may carry unintended weight with parents and children, caution should be exercised in reporting results, making evaluative statements, or giving advice.

15. When, in the course of research, information comes to the investigator's attention that may seriously affect the child's well-being, the investigator has a responsibility to discuss the information with those expert in the field in order that the parents may arrange the necessary assistance for their child.

16. When research procedures may result in undesirable consequences for the participant that were previously unforeseen, the investigator should employ appropriate measures to correct these consequences, and should consider redesigning the procedures.

17. The investigator whould be mindful of the social, political, and human implications of his research and should be especially careful in the presentation of his findings. This standard, however, in no way denies the investigator the right to pursue any area of research or in the right to observe proper standards of scientific reporting.

18. When an experimental treatment under investigation is believed to be of benefit to children, control groups should be offered other beneficial alternative treatments, if available, instead of no treatment.

19. Teachers of courses related to children should demonstrate their concern for the rights of research participants by presenting these ethical standards to their students so that from the outset of training the participants' rights are regarded as important as substantive findings and experimental design.

20. Every investigator has a responsibility to maintain not only his own ethical standards but also those of his colleagues.

21. Editors of journals reporting investigations of children have certain responsibilities to the authors of studies they review: They should provide space where necessary for the investigator to justify his procedures and to report the precautions he has taken. When the procedures seem questionable, editors should ask for such information.

22. The Society and its members have a continuing responsibility to question, amend, and revise these standards.

Appendix B,1.

Dear Parent:

Since 1967 the Infant Learning Laboratory at Michigan State University has been actively involved in studies of various aspects of infant development, parent-infant relationships and infant care. Our studies have explored learning, memory, attention, pacification, breast versus bottle feeding, and basic visual and auditory processes during the first year of life. Hundreds of babies in the Lansing metropolitan area have participated in these studies.

Our current project and one which will occupy our time for the next several years concerns various aspects of the baby's face. Some people have suggested that certain aspects of an infant's features (such as the size of the eyes, the fatness of the cheeks, the width of the forehead, etc.) as well as facial expression changes (smiling, frowning, etc.) may affect the way other people respond to him or her. It could be that some infants are more likely than others to elicit positive behavior from other people (such as parents) simply because of the way they look. Certainly, you may already have noticed differences in your reaction to your baby when he or she is smiling and when he or she is crying. We are planning to conduct a series of experiments designed to investigate such questions as: What makes one baby appear to be more cute than another? How do people respond to photographs of different babies? Do they smile, frown, look at the photograph for a long time? Do responses to infant photographs have any relationship to prior experience with infants? In order to conduct these experiments we need to obtain photographs of a number of infants. We would like to ask your help by allowing us to photograph your baby and to use his or her photograph in future experiments.

Photographs will be taken by a professional photographer in the Psycholog Research Building on the Michigan State University campus. This photography is being funded by a Biomedical Sciences Support Grant. It will require only a few minutes to take your baby's picture. The photographs of your baby, along with photographs of other babies, will be shown to adults and children in various experiments during the next few years. All photographs will be referred to by number only, assuring anonymity. We will send you a print of your baby's photograph and summaries of the results of future experiments.

If you would like to have your infant participate in this project, please return the enclosed postcard promptly. Photographs will be taken on the dates listed on the postcard between 9:00 a.m. and 4:00 p.m. Indicate on the postcard which date would be best for you and you will then be contacted for an appointment. Please keep the enclosed map for directions to campus. If you have any questions about this project, please feel free to call either one of us at 353-3933 or leave a message at 353-8690.

Thank you for your time.

Appendix B,2.

Dear Parents:

As a parent you may have noticed that your baby already pays attention to the various interesting sights and sounds in his environment. Sometimes however, a particular event comes to bore him and he eventually ceases to attend to it. Interestingly though, a small change in that event or the occurrence of a new sight or sound will often renew his interest.

We at the Infant Learning Laboratory at Michigan State University have become interested in this particular facet of infant behavior. As part of an ongoing research program concerned with infant development we will soon be conducting a study with 3 month-olds which will deal with events influencing infant attention.

Briefly, each infant will be placed in a comfortable bassinette and given a variety of soft tones to listen to. We will then observe the infant's physical behavior and general body activity and record several physiological responses. For example, one thing we are interested in is the rate at which the baby's heart beats while he is attending to the tones.

I am writing this letter to ask you if you are willing to have your baby participate in this sutdy. We would like your infant to participate when he or she is close to 3 months old at a time of day when the baby is most likely to be awake and alert.

If you are willing to allow your baby to participate in our study please complete and mail the enclosed, stamped postcard. I will then call you and answer any questions you may have and arrange a convenient time for your infant to participate.

The Infant Learning Laboratory is located in room 103 of the Psychology Research Building on the Michigan State University campus. A map has been enclosed showing convenient access routes. If you have any questions please feel free to call me at 353-3933.

Thank you very much.

Appendix B,3.

Dear Parent:

As you know, one of the most important things that a child must learn in school is how to read. Yet despite the important nature of the reading process, we lack complete understanding of the mechanisms involved. What kind of mistakes do children make in reading? Are their mistakes simply more numerous than those of adults, or do they differ in more complex ways? Do children who are quick to respond on other tasks do better at reading than most children?

We are trying to answer these questions by examining the dimensions of words to which children pay most attention. We would like very much for you to allow your child to participate in this study along with many of the other children in his class.

Each child devotes about an hour, in two sessions of 30 minutes each. In the first session, we will examine his speed of responding on nonreading tasks; in the second, we will ask him to read some words while we record some simple physiological responses from sensors attached to his arm (these measurements are recorded automatically, and cannot be felt by the child, but our measurements will tell us the sorts of things to which he is paying attention). The study will not detract from his work in the classroom. This does not involve any sort of personality or intelligence test. Our previous work has shown that children enjoy participation in the study, and ultimately the information we learn will aid in the development of more effective methods of reading instruction.

The Holt School District Superintendent and the School Principal have already given their approval to the project. Please use the form below to indicate whether or not you consent to your child's being included in the study (your child cannot be included unless the form is returned to the teacher). If you need more information please contact Mr. Gilpin (353-3933), or the school principal.

We appreciate your prompt consideration for cooperation in this study. On request, an interpretive summary of the results will be sent to you at completion of the project.

Please check one of the following alternatives:

_____ I wish my child to be included in the study described.

_____ I do not wish my child to be included in the study.

Parent______________________________

Date______________________________

Child's Name______________________________

(Please return this completed form as soon as possible.)

Appendix B,4.

Dear Parent:

We are conducting a research project on the development of consideration for others in children. The importance of this subject is self-evident, and we would like to ask your approval for your child's participation in the project.

We are specifically interested in children's reactions to the feelings of others. Each child in the project will listen to some stories and then will be asked questions on their impressions of the stories. Information obtained from the children will be treated as confidential material and will be presented only as group data, without mentioning any names of children. The project will be conducted at the day-care facility, during the child's stay at the center, and each child will be involved for about 30 minutes.

The project has been reviewed and approved by the Research Committee of the Children's Board (the Parent's Board) of the Married Students Activities Unit, as of April 2, 1973. It has also been approved by the Department of Psychology at Michigan State University.

If you wish any further information, please call Mrs. Esther Cohen at 355-6009. We will assume that you have no objections for your child to participate in our study, unless we hear from you to the contrary by April 10, 1973 (either through a note to your child's teacher or a phone call to us).

Thank you very much for your cooperation.

Appendix B,5.

Dear Parents:

Empathy has been defined as an understanding of the thoughts and feelings of another. For my doctoral dissertation research, I am interested in studying the development of this type of interpersonal sensitivity with regard to peer interaction. That is, I would like to investigate the young child's ability to understand the thoughts and feelings of another child as presented in stories.

During the months of March and April, I will be carrying out my dissertation research at Spartan Village School and Red Cedar School. The Psychology Department at Michigan State University and the East Lansing Board of Education have approved the design and have consented to letting me use children in Spartan Village School and Red Cedar School as subjects in my study. Your child will be included in my study provided you agree to have him/her participate.

Each child in the study will listen to a series of stories in which characters will feel happy, sad, angry, or afraid. The child will be asked to identify the feeling and to tell why the character is feeling that way. The stories are not aimed at producing these feeling states in the child himself and so are not constructed to be upsetting or distressing to the child. The committee has approved each of these stories and has considered them appropriate to present to young children.

In addition to these stories, the child will be presented with a brief picture vocabulary test. The procedures should run about an hour in total time, though each child will be seen on two different occasions to complete the tasks.

If you have any questions about the study, please give me a call at either 355-8270 (office) or 351-1954 (home). I will return your call to follow up your request for more information if you are not able to get in touch with me. If you consent to your child's participation, please either mail the enclosed postal card to the address listed on the front or have your child return the card to his/her teacher by Thursday, March 21st. The research will begin on Friday, March 22nd. After the study is completed and written up (during the summer), the parents of all participants will be sent a summary of the findings, but not data on individual children.

Thank you for your cooperation.

RIGHTS, DUTIES, AND EXPERIMENTATION ON CHILDREN: A CRITICAL RESPONSE TO WORSFOLD AND BARTHOLOME

Stanley Hauerwas
University of Notre Dame

1. The Context and Limits of the Response

I do not intend to address the general issue of non-therapeutic research and experimentation on children. To do so would involve analyzing the issues of experimentation and the status and meaning of informed consent. I am including a brief essay as an appendix on the ethics of experimentation which argues that the basis for requiring informed consent should be our desire to preserve special relations such as that between parent and child rather than a commitment to the "autonomy of the person." I have included the appendix as I think it will be apparent that the argument there is similar to the issues I wish to raise concerning the papers by Drs. Worsfold and Bartholome.

My criticisms of Drs. Worsfold and Bartholome are but an extended commentary on Dr. Lebacqz's question raised in the Proceedings of the Commission on July 10, 1976. Dr. Lebacqz asked whether it is appropriate to speak of children having rights and then suggested that the language of duties might be more to the point. The force of her question is to remind us that generally we do not think of our children as subjects of rights that we must protect, but rather as our nearest neighbors to whom we have particular responsibilities. Dr. Toulmin, however, correctly points out that this kind of question raises so many issues that no one paper can even hope to analyze them properly much less settle them. However I at least want to try to elicit the context that

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makes Dr. Lebacqz question appropriate, and in so doing suggest why speaking of the "rights" of children is confused and perhaps morally misleading. Before analyzing Drs. Worsfold and Bartholome's arguments in detail I will try to suggest why I think we are drawn to use the language of "rights" and why it is inappropriate for an ethical analysis of the place of children as research subjects.

I should, however, say at the outset I am unclear what, if any, difference this kind of conceptual analysis will make for the policy our government should have in regulating research with and on children. It is quite possible, as we all know, to do the right thing for the wrong reason and rights language may give you as wise a policy as the language of duties. The issue, however, is not just what kind of policy toward research on children our society should institutionalize, but how the reasons for that policy manifest a morally appropriate attitude toward children and families generally. On such grounds I think I can show that the language of duties comes closer to reinforcing the kind of families our society should encourage to flourish.

1.1 The Social Presuppositions for "Children's Rights"

Even though I cannot show that any one policy toward research with and on children is entailed by either rights or duties language, I think I can show why we are drawn to employ the language of rights when trying to develop policies of this kind. Discussing the "right of children" in experimental contexts is but a further manifestation of the necessity for liberal societies to substitute procedural requirements for substantive judgments. Since it is the hallmark of liberal societies to allow each man and woman to marry for any reason and to have children for any reason then it makes little sense for such a society to try to include a normative conception of family and parental responsibility in its national policies. To employ the language of rights is to assume that children are simply one interest group among others and that they must have procedural safeguards to be protected from the undue advantage of other interest groups including their parents.

The requirement for parental consent for medical treatment of a child was orginally based on the assumption that the parents were those who knew and cared the most about the interests of the child. To be sure, this assumption opened the way for unwarranted interference or non-involvement by parents, but there was a check on parental misjudgment and malicious intent. That check was a normative view of the family that was shared by the surrounding community--namely the patterns of parental responsibility were widely shared, as were expectations concerning how one ought to care for children.

The employment of the language of rights is an attempt to find a substitute for the breakdown of our shared beliefs about how parents should care for their children. Parental consent in such a context is not a safeguard against powers the child would not otherwise know how to handle. Rather parental consent appears as an unwaranted and arbitrary power of parents over children. The use of the language of rights in relation to children appears in such a context to be a moral advance, since such putative "rights" seems to give the child standing over against the parents and society.

However in our enthusiasm for the renewed appreciation of the standing of children that"rights" language seems to entail we may have avoided entirely the issue of what kind of responsibilities parents should have toward their children. To answer that question involves knowing why people should have children at all; what level of care parents should be able to provide for the nourishing of children; and to what sacrifices and risks children should be exposed.

(The problem of exposing our children to risks is tied to our difficulty of knowing when it is appropriate to let children die. Indeed I suspect some of the worst cruelty perpetrated on children today results not from malicious intent, but from parental fear--confused about what we should do, we are tempted to do too much lest we not do enough. Indeed I suspect the urgency behind some forms of research on children derives from an unwarranted desire to keep our children alive beyond all reason. Death is never pleasant, nor is it anything that any of us should want, but there comes a time to die even for children.)

Of course there is another way to interpret the use of rights language in terms of research on children. To claim "rights" for the family can be thought equivalent to claiming that the state has no competency in matters dealing with the family--that freedom means that the state cannot and should not interfere with how families are formed and children raised. However this sense of "rights" is not germane to our case, because the subject of the "rights" is not the child but the family unit itself. "Rights" in this sense are not the claims of the child over against his or her parents and the state, but the entire family claims over against that of the state.

Moreover this sense of "the family's rights" cannot be maintained without qualification even in a liberal state. The state does have a stake in how families are formed and children cared for even if it is in a minimalistic sense. Parents cannot subject their children to cruel or inhumane treatment. Parents are expected to provide their children basic forms of medical care in order to protect them from serious infectious diseases. Moreover all, parents are obligated to educate their children in a manner appropriate to the parent's basic convictions. That these expectations be met is important to the continued functioning of the state.

The question of the use of children as subjects of experimental research is but one further activity in which the state has a responsibility toward children. This is especially the case when most of that research is directly or indirectly sponsored by the state through grants or agency involvement. It is not a question of whether the state is or is not involved with the family in these cases, but rather how the state should be involved and what conception of children and parental responsibility toward children should guide the state's policy. It is simply not possible for the state to act as if it can take a neutral stance toward the kind of responsibility parents have for their children. The language of the "rights" of the child may appear to be less controversial since it lets the state appear to be interfering less in how individual families are formed, but in fact it embodies a normative conception of the family that is destructive of some of the ways parental responsibility has been understood.

1.2 The Ethical Presuppositions of the Appeal to Rights

"Rights" language, however, appears not only to be a powerful idiom for consideration of these issues because of its social context, but also because it is the language most natural to contemporary ethical theory. Most ethical theory, since Kant, has tried to base moral obligation on as thin a view of human nature and relations as possible. What we owe one another should be based not on being a father, citizen, or teacher but on our capacity for rational thought. The language of rights is a natural language for such a theory, since morally rights are those claims that can be made irrespective of any special, historical, or personal relations in which we may find ourselves. (For a fuller development of this point see David Burrell and Stanley Hauerwas, "From System to Story: An Alternative Account of Rationality in Ethics," Hastings Center Publication, Forthcoming)

Put differently contemporary ethical theory has avoided dealing with issues such as the nature of the family exactly because its presuppositions make the family appear odd or at least not an ethically interesting object for analysis. For as MacIntyre has reminded us the language of rights is of recent origin and presupposes an individualistic understanding of man in society. The language of rights begins with "the concept of a collection of individuals and the problem of how out of and by individuals social institutions can be constructed." (MacIntyre, "An Essay prepared for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on the subject of How to Identify Ethical Principles," p. 18) The development of this kind of ethical theory has appeared natural and persuasive for as MacIntyre points out "in a crucial sense the relationship of most people in our society has become that of stranger to stranger." (p. 35).

This conception of society makes it appear that all social relations in one way or another take the form of a contract--all human relations are commercialized. But if MacIntyre is right then the use of "rights" language in relation to the family yields an understanding of the family as a contractual society of individuals. But that is exactly what it is not. In the language of Aristotle the family is a "natural" institution. "Nature" does not mean that it is clear that we must form families in order to satisfy basic desires, but rather the family is a primitive institution in relation to the state. We do not ask to be born into families, we simply are born into families of one kind or another. In a decisive sense the family is not a voluntary institution and the kind of responsibilities that accrue in it are thus different.

Moreover because of its peculiar interest to free ethical judgments from all contingent beliefs and practices contemporary ethical theory has failed to pay sufficient attention to the kind of moral role implied by the notion of "child." It has assumed that we simply know what we mean morally when we speak of children--namely empirically those that are smaller, younger, dependent, and less "rational" than adults. But if the argument above has been correct you do not even know what it means to be a child until you have some normative understanding of what it means to be a family. "Child" and "children" denote moral roles that are relative to a set of expectations and pratices that we call family.

It is certainly true that the moral meaning of being a child has changed through history and differed from one society to another. But that is simply to reinforce the point that morally the notion of family and child is dependent on a moral and historical development our society has inherited and changed. I am suggesting that basic to that history has been the assumption that parents had duties toward the child--not simply because they were responsible for bringing the child into existence-but because being a parent was to perform an office for the community to see that the child was cared for and educated in a manner that was appropriate to that community.

Perhaps the point I am trying to make can be best illustrated by calling your attention to the place of the family in some of the more conservative religious traditions. For the orthodox Jew there is no question of whether he or she should or should not have a family--children are a religious duty for the continuation of the people of Israel. To be a parent in such a context means that you have duties to fulfill--you must care for the child in a manner appropriate to making the child a full participant in your community. That may not mean giving them all the medical care available; learning the Torah may in fact be more important. As a parent you do not impose your will on the child in an arbitrary manner, but rather you act as an officer of the community to initiate the child into the practices of that community. The child does not have "rights" qua human being, but the child does have a standing as an independent agent in relation to his parents as they are both subject to the community's expectations. Morally the meaning of "child" is relative to the interests and needs of the community as mediated through the family. You are no longer a child when you can observe the Torah.

I am not trying to defend any one view of the family by appealing to this example, but rather I am trying to make the conceptual point that any appeal to family or child as moral entities requires a set of historical presuppositions. In other words to speak of family and child is exactly to speak of duties of parents and children toward one another that are grounded in the concrete expectations of particular communities. But it has been exactly the pretention of modern ethical theory that it could free itself from such historical presuppositions and ground moral judgments in man's "rational" nature qua man--i.e., as if we were strangers to one another in the sense that we share no history or common purposes. But that is exactly to isolate the family from any context in which it morally can make sense.

In summary I have tried to suggest that modern ethical theory has tried to deal with the issues of the status of children as research subjects in the language of rights because such language best suits its methodological commitments. For the language of rights appears to provide a way of giving children a moral status without presupposing any arbitrary and particular conception of parental responsibility. However, I have tried to suggest that even though such a strategy may have some plausibility in a society where parental responsibility in unclear and ambiguous, the strategy in fact embodies assumptions that contributes to the distortion of the family as a moral entity.

1.3 The Continued Cogency of "Rights" Language

The argument I have made so far has been something of a broadside. It is my hope that my criticisms of Dr. Worsfold and Bartholome will help qualify the position I have presented. However in the interest of clarity I will try briefly to separate out some of the questions involved in my argument.

First there is the question of whether "rights" language is conceptually, politically, and morally appropriate in any case, let alone in reference to children. Even though I do not wish to claim that all "rights" language is conceptually unitelligible, I do feel that the attempt to make "rights" the moral foundation for social and political life is mistaken. As MacIntyre suggests there is an arbitrariness to all claims of rights that emerge when we ask "what rights all human beings possess, a question to which both the American and the French revolution professed to give an answer. To life, to liberty, to happiness--to property, to a job, to a fair trial. . .what criteria qualify for inclusion in the list, what for exclusion? The arbitrariness emerges once more if we ask under what conditions each of our alleged rights is defensible. When right clashes with right or with the public interest or with the greatest happiness of the greatest number which is to give way to which? We only do not drown in a sea of uncertainties by resorting to a fraudulent assertion and counter-assertion. Note that I am not suggesting that all claims to moral rights at all times are arbitrary and unfounded. But claims to right have only not been arbitrary when they have been asserted in specific historical contexts in which a good was in danger of being sacrificed by an infringing power. The claim to a right is then essentially negative in form. The agents of the infringing power are told that they have no right to deprive us of some good." (33) MacIntryre concludes therefore that rights only have force within certain types of contexts.

Moreover when "rights" are taken to be the fundamental moral reality we are encouraged to take a perspective on society that is ultimately degrading. No society can exist when its citizens' only way of relating is in terms of non-interference. The language of "rights", especially as it is displayed by liberal political theory, encourages us to live as if we had no common interest or beliefs. In MacIntyre's language it trains us to regard each of our fellows, even finally our children, as strangers. Traditionally strangers are those that come from a different community now they are our neighbors. This is a formula not only for the disintegration of society but of the disintegration of the moral self, as it trains us to pursue our interests as ends in themselves.

Therefore even though I do not reject all use of right language, as a basic moral language I find it insufficient on grounds of social theory. Secondly, however, it may not be a case of whether rights language in and of itself is appropriate, but whether such language is overused or used in inappropriate contexts. I have tried to suggest that there are good reasons for thinking that it is an overused language in our society and that in particular it does not apply to the familial context.

Thirdly there is the question of whether rights language, even if appropriate, can be applied to children. For "rights" presuppose a moral psychology which some have argued that at least very young children fail to meet. I have no wish to enter into this argument here as I think it would serve little purpose. However it should at least be pointed out that if rights are to be claimed for very young children the Commission will need to provide counter arguments to those who argue that young children neither have the rational capacity or the "interests" necessary to have rights.

It is at least worth mentioning that from the perspective I have tried to develop, I regard this last issue to be a category mistake. Morally the issue is not what claim children have on us, but what should our responsibility be to them irrespective of their ability to make a "claim." We clearly feel, for example, that we owe certain kinds of care to animals even though they have no claim upon us. We do so not because of their capacity or lack of capacity, but because of the kind of people we wish to be and the kind of relation we can form with animals. (I owe this point to Dr. David Solomon of Boston University)

In spite of these arguments, however, I expect the language of rights will still hold great attraction for members of the commission. For the language of rights is the historic language of our society and any policy decision seems more persuasive when it can be framed in those terms. Also as I suggested above rights language in today's social context appears to serve the child's interest. Moreover if my argument has at least been partly right it would seem to require the commission to appeal to a normative conception of the family to which not all in our society would adhere. Properly many on the commission must wonder if they have the moral grounds to take that kind of position. The language of "rights" at least appears as a compromise language that diverse groups can interpret in their own way. However, if the commission decides to use the language of rights, I hope the position suggested here will at least mean that such language is employed with qualification.

2. Response to Worsfold

Dr. Worsfold, drawing on the work of John Rawls, argues that children are entitled to rights of their own in a manner that qualifies paternalism. This is certainly an advance over the position of Hobbes, Locke, and Mill, but fortunately these are not our only alternatives. I do not wish to challenge Dr. Worsfold's use of Rawl's position to make the case for children's rights, but it should at least be pointed out that Rawls' position has come under heavy and at least partially successful attack. It would seem odd to base the moral standing of children in respect to experimentation on a theory that has proved less than convincing to many. For example it can be asked why Dr. Worsfold choose Rawls rather than Nozicks' entitlement theory of rights.

Moreover I think it can seriously be questioned if Worsfold is correct to assume that children are included in the initial social contract on Rawls' grounds. He is certainly correct that Rawls "age of reason" is ambiguous, but it is unclear that one can use the ambiguity in favor of including children in the original contract. I suspect that Rawls in order to include children will need to make an argument similar to H.D. Aikens' even though Worsfold criticizes the latter. (For a good exposition of this problem see Ron Green's argument that Rawls's position requires something like the idea of conferred rights. Journal of Religlious Ethics, Spring, 1974)

However these are not the aspects of Worsfold's argument that concern me the most. Rather I wish to call particular attention to Worsfold's view of moral autonomy. Worsfold's view on this matter seems similar to the July 29, 1976 draft "Children as Research Subjects" by the National Commission. On page seven of that document it says, "The moral and legal problems that arise over research involving children spring, fundamentally, [I never trust the use of that word] from the principle of respect for persons, and for the autonomy of persons." I shall try to show, by criticizing Dr. Worsfold, that this sets the issue wrongly by making "autonomy" the central moral norm, a position that is neither psychologically realistic nor morally central.

Because Dr. Worsfold makes autonomy central to his conception of the moral life his use of the word "paternalism" is always perjorative. The assumption is that paternalism may unfortunately be necessary, but that ideally our relation to one another should be one of complete non-dependence. This ideal is supported by the psychological fact that those who try to "help" the weak or young often do so as a means of gaining and holding power. Obviously Dr. Worsfold is articulating an intuition we all share in various degrees. However the pervasiveness of the assumption that such autonomy is a desirable goal does not make it such.

For in fact the achievement of such autonomy is but another way to describe loneliness. In this respect I suspect that Dr. Worsfold, in spite of his criticism of Hobbes, continues to share Hobbes' assumption that the primary term of relation between parent and child is power. (This is illustrated by his analogy between parents and colonialists.) The only question is how to secure for the child some of the power that parents currently claim. It would appear if we can make a case for children's "rights" at least they will have some standing against their parents.

But surely this is a formula for the destruction of the child--namely it is to turn the child into an adult. The trust, love, and care required by the child cannot be replaced by giving the child "rights" without destroying what being a child means. I am aware that Dr. Worsfold is not recommending that rights language replace the language of trust and love, but I am suggesting that he seems to assume that caring for the child in those terms tends to be inherently paternalistic and thus lessens the autonomy of the child.

In contrast to Dr. Worsfold it is my contention that there is nothing wrong with "paternalism" once we see that the development of autonomous beings is not the culmination of the moral life. Rather the goal of parenting is the creation of people who can enter into trustful relations because they have learned not to fear the other as a threat to their "autonomy." To be sure such people have the capacity of self-determination, but this capacity is not the same as being "autonomous". It is rather the ability to receive as well as to give without using receiving or giving as a means to control the other.

In order to make these remarks more concrete let me again call your attention to the more traditional form of family. We tend to think that the idea of raising children to be autonomous is an objective value to which all rational people should adhere. But think of the Orthodox Jew. They are not raising their children to be autonomous especially if that means when they reach the age of reason they can choose whether or not to become a Jew. To think of being or not being a Jew as a matter of choice is already to betray the tradition. Rather they raise their children to become the best that they know--namely Jews.

To call such a process "paternalism" in a negative sense is simply question begging and special pleading. It is not a question of paternalism but parental responsibility to initiate their children into the best form of life that they know. Not to do so would either be cowardice or irresponsibility. Caring for children both in terms of their health and their education is not a question of paternalism, but of what kind of responsibilities parents should have given the expectations of the community in which both the parents and child exists.

In this respect Dr. Worsfold's claim that often parents do not know what is best for their children and that children are capable of making sensible decisions for themselves is simply beside the point. It is of course true that some parents, irrespective of what community they are part of, do not know what is best for their children. The important claim is that they should know what is best for their children in matters of importance. No doubt many orthodox Jewish children do not feel it is in their best interest to be orthodox Jews, but that is not relevant to the issue. On important matters children simply do not have interests until they have been taught what interests to have.

Nor should this position be interpreted as denying all respect and moral standing toward children. It is simply not the case as Dr. Worsfold suggests that our respect for a child's independent status is dependent on whether the child does or does not have "rights." A "right" is not the same as a "standing" that requires respect. Indeed in orthodox Jewish families the child is highly respected and honored exactly by being treated as a participant in the community--that is as being able to perform his or her function as a fellow Jew.

Thus in spite of its prevalence today the issue of paternalism is a misleading way to state the moral issue of parental responsibility to care for and nurture children. To be a parent is to perform an office for a community to see that the child finds his way into the moral best that the community has to offer. Of course, the parent does not or should not have complete power over the child, since the child also has a standing in the community apart from the parent. Such a standing cannot be guaranteed by the language of rights, but rather depends on the moral substance of that community and how it has learned to regard children as valuable beings.

In this respect Dr. Worsfold rejects far too cavalierly the suggestion that adults and children are bound together by being able to suffer. (Which is not as he suggests just proposed by those of religious persuasion, as many utillitarians make a somewhat analogous argument.) Indeed it may be that it is the capacity of children to bear the burdens of being a member of a community that constitutes our common bond. It is not a question, however, of suffering or not suffering, but what we suffer for whether we be adults or children. (Worsfold seems to assume that suffering is ruled out as a basis for respect, because it would include prisoners, invalids, mental incompetents, and even animals. Indeed that would seem to me to be its most attractive aspect. Otherwise I cannot see how "rights" avoids finally being an ideology for the strong to assert their status against the weak. On the place of animals as possessing claims see Peter Singer, Animal Liberation.)

3. Response to Bartholome

My response to Dr. Bartholome will be less clear cut than my response to Dr. Worsfold. For not only does Dr. Bartholome's papers cover a broader range of topics and concerns, I am also very sympathetic to some aspects of Dr. Bartholome's position. My analysis and argument concerning his position will primarily be an attempt to suggest that his conclusions do not require the language of rights in the way that he thinks they do. I will primarily comment on Dr. Bartholome's paper, "The Ethics of Non-Therapeutic Clinical Research on Children," but I will refer to "Proxy Consent in the Medical Context: The Infant as Person" when it develops or goes beyond the position in the former paper. In order to simplify my reference to each paper I will simply number them (1) and (2).

In (1) Bartholome begins by defining a child as a person below the age of 14-16. As I suggested above this kind of designation of children assumes that knowing whether someone is or is not a child is an empirical question. But this is clearly mistaken. "Child" is a notion that first depends on conceptual and moral analysis in order even to know what empirical characteristics will count as locating a child. The "age of reason" criteria suffers from the same confusion. This is not to argue for a functional understanding of

Children--a child is only such in relation to certain assumed tasks or relations, but it is to suggest that often our assumption that we know what a child is depends on unexamined premises. Moreover not to raise this kind of question makes us forget that morally "childhood" is dependent on our understanding of family and community.

In (1) Dr. Bartholome argues that consent is the key moral issue on which the morality or immorality of experimentation on children rests. However this position is somewhat qualified in (2) as he claims that consent is never a sufficient condition to justify medical intervention or experimentation. But he seems to assume that while not a sufficient condition consent remains a necessary condition for any therapy or research. I will not take the time here to go over the same ground concerning consent that is included in the Appendix; however I do want to make a few comments about Dr. Bartholome's understanding of the criteria of consent.

I want to question Dr. Bartholome's justifications for making consent the primary issue in medical therapy. He first appeals to Ramsey's attempt to base consent in the "canon of loyalty" between physician and patient, but Ramsey's own position in this respect is less than clear. Ramsey appeals to the Jewish and Christian sense of "covenant" to provide a paradigm for his "canon of loyalty," but it is not clear how the analogy between God's covenant with his people and the "canon of loyalty" between doctor and patient is justified or illuminating.

Like Ramsey, Dr. Bartholome also appeals to consent as a necessary correlative of our respect for "persons." But the Kantian sense of "respect for persons" seems to be committed to a more individualistic conception of human dignity than the communtarian conception of "covenant" can allow. To be a member of a covenant is to be loyal to the commitments fo a community in a manner that renders suspect the placing of individual interests before those of the community and the object of loyalty that the community serves. In other words I am suggesting that Ramsey and Dr. Bartholome may have some difficulty having their covenant and Kant too.

In (2) Dr. Bartholome suggests that the opaqueness of others and the humility appropriate toward others' interests is a condition for making consent central for any medical intervention. However this is a pragmatic justification that suggests that if the opaqueness is removed, as it might be in certain cases, then consent can be overridden by other interests. I raise this issue because I feel Dr. Bartholome's paper illustrates the general unclarity of why consent is made the central issue for medical intervention. I do not wish to argue that consent is not important, I am simply suggesting that in spite of the common assumption of its centrality no convincing arguments have been established. Without a clear sense of what kind of justification should be given for consent we cannot anticipate how consent should be institutionalized within medical practice and research.

It is my hunch that consent has become central for us, not because it is a fundamental category, but because in a liberal society it is the only way we have to protect ourselves from one another. In other words, without denying that consent in any society has some moral force, I suspect that its moral force in our society arises as much from political reasons as from moral.

Until these issues are clarified I think the issue of proxy consent must remained confused. I would at least suggest that proxy consent, which Dr. Bartholome interprets to be primarily an attempt to protect the child, can equally be seen as an attempt to protect the integrity of the family unit. In other words proxy consent as an institution is one way to insure that whatever is done to the child it is done in accordance with the moral convictions and traditions of that family. The problem is that proxy consent in our society has become a power in the hands of certain parents whom we fear have a corrupt moral convictions about the kind of care should or should not be given to children. (a situation amply illustrated by many of Dr. Bartholome's "cases".)

This is, of course, the basis of Dr. Bartholome's criticism of McCormick's defense of proxy consent in non-therapeutic context. Though Bartholome does not develop it I suspect that he could make much more of the difficulty of distinguishing between therapeutic and nontherapeutic contexts. In (2) he suggests that this is an extremely difficult distinction to draw in practice. His judgment in this respect can be amply documented for example, in the treatment of young children suffering from lukemia; it is by no means clear when treatment for one child conforms or does not conform to "established and accepted medical practices." This problem is not occasioned simply by the doctor's need to learn more to help future patients, but by the fact that every patient is different in a manner that makes "standard" practices suspect for that patient. (For an extraordinary depiction of the bind parents are caught in when they subject their children to extraordinary therapies in the hope it may do "some good," see Peter DeVries' novel, *The Blood of the Lamb*.)

Generally, I think that Dr. Bartholome's criticisms of McCormick are correct, but I think that Dr. Bartholome's own position may have some of the same difficulties as McCormick's. For to say that children can participate in "non-risk" experiments because it will contribute to their moral growth is very similar to McCormick's position. Dr. Bartholome, therefore, must answer the question he asks McCormick--namely it might be a good thing for children to participate in such experiments, but who has the status to say they ought to do what is morally superogatory?

In this respect I think that Dr. Bartholome has failed to note one ambiguity in McCormick's position that is important. McCormick phrases his argument in terms of the common good, but that is clearly too vague as it seems to imply that there are some things we can expect children to do for the good of the greatest number. That would make his argument appear very similar to certain utilitarian arguments that say in certain circumstances the good of the community justify imposing greater risks on particular members of the community.

However, McCormick has another argument that does not depend on the language of "the common good" at all. Rather he says in certain contexts we know what the child ought to choose for himself--self-preservation and health--irrespective of the interests of the community. In this respect I think that Bartholome's worry here and in (2) that we cannot know the child's real interest is beside the point. McCormick is not claiming that we know this individual child's interest, but rather that we know generally certain basic goods that all people have in common (which is not the same as "the common good") which we can act on with assurance.

However this argument still proves less than convincing because of the vagueness of terms such as self-preservation and health. Morally we do not choose to survive as an end in itself, but because survival provides the conditions for the achievement of other moral ends. The question is whether children are not, like adults, forced at times "to choose" between those ends that we survive for and survival. I suspect good communities assume that children are those who should be protected from having to make that choice as long as possible. (This may be the source for why we want to use rights language--namely to remind ourselves that children require special protection--unfortunately however the language of rights has become an end in itself rather than a reminder of the why we wish to protect children in the first place.) However that does not mean at times it may be necessary to make the decision for the child--it is better to die as a Jew than to be raised as a Gentile.

What this indicates is that children, even infants, can have a moral role in a community even before they are agents. Dr. Bartholome wants to make a child's contribution to a community dependent on his or her maturation level, which surely is important, but I am suggesting that at times communities can choose in a morally humane manner to assume that the child has moral standing in the community even when the child cannot choose that standing on its own. Formally this position bears some similarity to McCormick's, but unlike McCormick I think that there is no way to determine what interests the child should have as a member of the human community qua human community. As humans we share a moral capacity and needs, but such capacity and needs are not sufficient to ground concrete moral judgments--that requires the convictions and practices of actual communites.

My argument can be illustrated in respect to Bartholome's criticism of McCormick's suggestion that we may all have a responsibility to participate in non-therapeutic research. Bartholome suggests that this is to assume we have a moral obligation to perform acts of supererogation, and that this assumption is unwarranted. However there is no way apriori to draw a distinction between practices that are obligatory and supererogation. Such distinctions depend on the concrete convictions and practices of particular communities. If medical research plays a crucial role in advancing the primary purposes of a community, then the assumption that everyone should participate in that research may make sense. I suspect that such an assumption cannot be sustained in our society and as a result Dr. Bartholome's conclusion certainly seems warranted. This is especially the case as we have no reason to subject some to undue risks now in order that future generations will be free of certain kinds of diseases.

If the position I have been trying to develop is at least partially correct it means that Dr. Bartholome's appeal to the Kantian notion that we should always treat another as an end and never as a means is simply too simple. The question is never whether we use another as a means, but whether the end is commensurate with their good as a member of a morally healthy community. Nor is the appeal that we ought to treat another as a person, that is as an end in themselves, sufficient. For example Dr. Bartholome suggests in justifying intervention in case 4 of (2) that not to require the parents to repair the infants club feet would be violating the "infant as a person." But the issue is not whether the infant is or is not being treated as a person, but given what we know about how important it is to walk we think that parents should provide proper care. In other words such a decision has little to do with whether the infant is or is not a person, but rather is dependent on our normative understanding of the kind of care parents ought to give children in order to secure as satisfying life for them as is possible. The moral issue is not that the child in case 4 has a "right" to proper medical care, but given what we know about care for club feet the parents have a responsibility to give that kind of minimal care to the child.

Appeals to the notion of "person" as a way to underscore parental obligations to their children is therefore unnecessary if not misleading. It simply introduces the question of whether children are or are not person--and that is a misleading question. We care for children because they are children not because they are persons. (For a further analysis of this issue see my "Must a Patient Be a Person to be a Patient: Or My Uncle Charlie May Not Be Much of a Person But He is Still My Uncle Charlie," Connecticut Medicine, 39, 12 (December, 1975, 815-817).

A similar kind of problem is involved in Dr. Bartholome's appeal to rights language in (2). I do not necessarily disagree with his position, but I simply do not think he needs rights language to make it work. In fact, however, it is difficult to know exactly what Dr. Bartholome means by rights. He sometimes speaks as if rights are correlative or our "membership in human community," but then he suggests that rights require a community with "certain constitutive characteristics." (13) It may be that Dr. Bartholome can have it both ways on this matter, but if so he must be able to spell out in more detail how a particular community's characteristics are dependent on our membership in the "human community."

Or again he argues that rights language makes sense as a way to indicate that an infant has a claim to be fed, have adequate shelter, and have other basic needs met. In other words, the infant has claims over against his or her parents to provide or to try to provide for the infant's needs. If the parents cannot do so then the state can step in to see that the infant is cared for by aiding the parents or by seeing that the infant is cared for by those that will meet the infants needs. I have no inprincipled objection to rights language being used in this manner if it is clearly seen as dependent on the more basic language of parental obligation. In other words such "rights" are simply ways to mark off basic parental roles and obligations that any parent, regardless of their peculiar convictions or practices, can be expected to meet by the state.

However Dr. Bartholome obviously has a more substantive claim in mind as he argues that these role dependent rights are dependent on what Hart calls "general rights." (15) In Dr. Bartholome's words, "the infant must be recognized to have the right to be treated as a member of the human community, as a person." But as I have tried to suggest being a member of the human community morally even with a dime will not buy you a cup of coffee. The recognition and respect due infants and children are not insured by posting a "right" dependent on being a member of the human community, but by being the kind of community that has learned to value children as members of that community.

[Dr. Bartholome also argues that an infant on the same grounds has a right to the care a physician can give. I find this an extremely doubtful assertion as the mere existence of doctors does not mean that each individual infant has a claim on their care (which of course raises the further question of the extent of care that can be claimed.) It seems best to see the care that the physician is obligated to give as an extension of the parent's basic responsibilities. In other words contrary to Bartholome's suggestion the infant does not have a direct claim on the doctor, but rather has a claim on the doctor as mediated through the responsibilities of the parents.]

Like Dr. Worsfold, Dr. Bartholome is concerned that infants and children have a basis for being treated with respect and care. But I think that Dr. Bartholome fails to specify what normative conception of family and community makes such respect morally compelling. Both positions require that children be turned into potential adults in order to be respected, but that is to fail to treat them for what they are--i.e., children.

For example Dr. Bartholome suggests that the "end of parenting is formation of highly developed persons, i.e., persons who are free, autonomous beings capable of reasoned choices, it is essential that infants and children be treated as persons." (16) But again it seems to me that this posits a morally false sense of autonomy on which our respect and treatment of children depends. This poses some difficult problems in respect to children who are retarded as they will never be able to achieve the kind of autonomy that Dr. Bartholome thinks crucial to being and becoming a "person."

Dr. Bartholome thinks that unless the "rights of infants and children" can be established on the grounds of their membership in the human species then there is no way to justify intervention on the behalf of abused or neglected children. But as I suggested above such intervention does not require a doctrine of rights of the child against the parents, but a normative conception of parenting and the family. That does not mean parents own their children, but rather they have responsibilities that are correlative to their community's sense of the importance of children.

4. Conclusion

In conclusion I would like to say that in spite of my criticism of Drs. Worsfold and Bartholome, I think that they are grappling with issues that are well nigh insoluable in our cultural situation. No philosophical device whether it be in the language of rights or some other alternative is sufficient to lead us out of this dilemma. For we live at a time when we simply are not clear why we should have children or what we should do with them once we have them, and talk of formal "rights" will not provide the answer.

In traditional religious communities it was claimed that children were a gift of God. They were neither the property of their parents nor of the community. Rather parents and community were but the way God's care was mediated to the child.

With the loss of that sense of providence the child became the possession of the parent--for after all it was by the sheer exertion of parental will that the child had existence at all. Such "paternalism" could be extremely beneficial to children but at the same time it always contained the potential for despotism and arbitrariness.

A natural way to place a check on the unbalanced power of the parent was to assume that if God does not own the child, and the parents do not own the child than the child must own himself (or the other alternative that the state must own the child). But what all of this ignores is that it is not a question of ownership at all, but rather whether we can be the kind of people who can welcome new life among us even when such life is destined to change our own. The language of rights I suspect will teach us little about the kind of skills we need to train ourselves to have to take on that kind of task.

I have been able to write with more freedom than the commission can formulate its policy. I can write as if an ideal world is possible, but you cannot. I can write as if experimentation on and with children might be a possibility if certain assumptions about parenting and community is present, but you cannot. Moreover I have suggested that the most readily available language in our society to deal with these matters has some definite drawbacks. I frankly do not know what kind of policy I would recommend if I were on the Commission.

However I think I would at least try to write the report in a manner that manifest the moral unclarity with which we are faced. Too often our ethics and our policies are formed as if we are clearer than in fact we are. By stating the issue ambiguously at least you could signal to the research community, the government, and the parents that make up the American people that morally we are not O.K. when it comes to our assumptions about the place and role of children in our society. In such a situation it does not seem to be an unwarranted conclusion that we should experiment with children in the same way that procupines screw--very, very, carefully. A more radical suggestion would be that in the light of our moral unclarity, which after all is not just a problem of theory but of ourselves, that we should not use children in non-therapeutic experimentation. Or finally it might be interesting to say only the broadest guidelines can be drawn and that the justification of each experiment depends greatly on how the experimentors can morally articulate their purpose as a way to serve particular people--the health of the nation will not do-- and why the children and parents of the experiment have a stake in that. Namely it is as important that protocols be moral documents, not just in the sense of consent, as they show that the experiment is scientifically well conceived. Protocols, like judicial decisions, should have moral dicta that helps remind us how they are justified in the light of our basic convictions.

6

NATIONAL MINORITY CONFERENCE ON HUMAN EXPERIMENTATION
CONFERENCE PAPERS

CHILDREN AND THE INSTITUTIONALIZED MENTALLY INFIRM

Henry W. Foster, Jr.

CHILDREN AND THE INSTITUTIONALIZED MENTALLY INFIRM

Crystal A. Kuykendall

RESOLUTION AND RECOMMENDATIONS OF THE WORKSHOP ON CHILDREN

CHILDREN AND THE INSTITUTIONALIZED MENTALLY INFIRM

Henry W. Foster, Jr.

On July 12, 1974 the United States Congress approved public law 93-348 (H.R. 7724) amending the Public Health Service Act to establish a national commission for the protection of human subjects of biomedical and behavioral research. As a part of its charge, the Commission is to conduct comprehensive investigation of the legal, social, and ethical implications of biomedical/behavioral research and technology involving human subjects. Guidelines and recommendations are to be made to the secretary regarding the application of these guidelines to biomedical/behavioral research.

The duties of the commission will be multiple and will be concerned with the issue of informed consent-giving and programs involving children, prisoners and the institutionalized mentally infirm. Additionally, review of existing protective regulation will be conducted alone with investigation of the nature, extent and purpose of research involving living fetuses and alternate means for achieving such purposes.

My charge today as a participant in this National Minority Conference on human experimentation is to examine ethical issues concerning research in children and the institutionalized mentally infirm especially from a minority perspective. And indeed such an insight is vital given the fact that the biomedical research community so often falsely and unimaginatively assumes a common national life-style in its research design. This failure to recognize the heterogeneity of the texture of this nation's social structure is in great part responsible for our being assembled here today.

Before delving further into this issue, it is appropriate to render some clarification as to what constitutes human medical research and to establish a definition of the child. Defining the institutionalized mentally infirm presents no difficulty. It is an all or none situation, however, on the other hand, if I had to define the state of mental infirmity my task would be immensely more difficult. When for example is a patient non compos mentis? How crazy is too crazy? When does the neurotic individual become incapable of providing informed consent? However, for the sake of my discussion in this manuscript, as will become evident later, the significance of the institutionalized mentally infirm, as regards their suitability for biomedical research, becomes significantly diminished.

In its broadest sense, medical experimentation on human beings is capable of occurring and indeed does occur in practically any setting where medical care is rendered. This may be in the physician's office or in the patient's home when for example the doctor has recommended, "take a couple of days bedrest," as might be advised in the case of a mild undiagnosed febrile reaction or a minor gastrointestinal upset. The issue then of biomedical experimentation in humans is basically a matter of degree and extent rather than kind. Yet for our needs, I believe the definition furnished by Irving Ladimer is suitable and is defined as "deliberate inducing or alterating body or mental function, directly or indirectly, in individuals or in groups primarily for the advancement of health, science, and human welfare."[1] Such a broad definition rather well encompasses human experimentation in a context appropriate for this Conference.

Again, for the purpose of this Conference we will find the greatest utility will be achieved by utilizing the definition for the child or children as that set forth in Public Law 93-348. It reads as follows:

> Individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the juridiction in which the research is to be conducted.

Although the definition is clear and concise and the confines are clearly drawn, the issue of informed consent-giving on the part of a minor child remains unresolved. Clearly an infant or child of 5 or 6 years cannot provide an informed consent. And in contrast, surely the adolescent of 16 or 17 years should be able to make this judgment.

Last February in Washington, D. C. the Academy Forum under the auspices of the National Academy of Sciences began to grapple with the board problem of human experimentation by convening a conference, "Experiments and Research in Humans: Values in Conflict." Considered at that two-day conference were selected groups similar to those populations at risk upon which we focus today. As a participant in that forum, I attempted to identify those groups placed at greatest risk because of their "captive state" and accordingly, recommended that a moratorium be effected in their behalf by stating and I quote, "it is my belief that those clearly incapable of providing voluntary informed consent constitute this group. They are the functionally illiterate, the senile, those who do not command the English language and certainly the mentally incompetent."[2] Therefore, it is my strong opinion that mental retardates, be they institutionalized or otherwise, be exemp from all non-therapeutic research.

As you will note, children as a group are not included in the recommended exemptions. There clearly exists the need to continue the search for better therapies and cures for the many childhood diseases that are so prevelant and devastating. Some examples would be the leukemias, bone and kidney cancers, congential cardiovascular anomalies, sickle cell disease just to mention a few. Our charge here today is to help structure a milieu in which needed research can occur wherein risks to blacks, the poor, or other disadvantaged groups are maximally reduced.

Essential to all good research design is the maintenance of the balance between risks and benefits. Disruption of this balance results in either excessive risk to patients or an abatement of productive research; productive research often bears an inverse relationship to patient safety. These two values as they apply to biomedical research are viewed as the scientific priority of discovery on the one hand and humane therapeutic treatment on the other. This has come to be known as the dilemma of science and therapy. The avoidance of future experimental misadventures such as the now infamous Tuskegee syphilis study can in my judgment best be achieved by reviewing the characteristics of those research subjects who are most susceptible and who in the past have been victims of such untoward research--such as the categories I listed for exemption. How then do I fail to include children in those groups selected for exemption if by my own admission I cite the requirement of being able to provide an informed consent as a prerequisite to any biomedical research participation? Under these circumstances, the same criteria for exemption in the case of the child or the fetus would appropriately reside with the parents who constitute their biological representatives and in my opinion their legal representatives as well. However, because of the differences in life styles between blacks and whites, quite possibly adulthood as a practical matter begins earlier for the former group and accordingly, a more workable definition of childhood may be appropriate.

As a black medical educator, I cannot help but feel some ambivalence on the question of biomedical research. Research or the absence thereof is inexorably tied to the financing of American medical education. The total number of medical students enrolled in United States medical schools in the academic year 1972-1973 was 13,667. Of this number 957 or about 7% of the total were Black Americans.[3] Of greater significance though is the fact that over half of these black students were enrolled in Howard and Meharry, thus reducing to less than 3% the percentage of black students in American medical universities exclusive of these two predominantly black institutions.

The need for increased numbers of black physicians is greater now than it has been for many years. Theodous Thompson has recently stated, "However an examination of some recent studies on the distribution of black physicians in the United States shows that the black physician to black population ratio is less today than in 1942 even on an aggregate basis."[4] Understandably, any steps which threatened to reduce our academic productivity causes me great concern. Certainly the overall relationship of biomedical research and the financing of medical education is in need of detailed study. The tremendous pressures which exist with respect to the sustained thrust for the research dollar may very well create an atmosphere which frequently is to the detriment of biomedical research subjects.

A hypothetical case I believe will best serve to illustrate many of the problems of biomedical research preculiar to black children.

HYPOTHETICAL CASE

Garvey's syndrome is a disease of the central nervous system characterized by the triad of progressive loss of vision, neuropathy, and ataxia. The disease usually becomes manifest in the first two years of life and death has claimed 15% of its victims by late adolescence. The disease continues to progress wherein approximately 40% of the subjects have succumbed by age 50.

The disease effects one in 2,000 and all ethnic groups within the American population are at equal risk for the disease. Males are affected approximately one and a half times more often than females. Some limited symptomatic relief from the disease is available but there is no know cure.

A team of competent research investigators at the local University Hospital have for sometime had an interest in Garvey's syndrome. After 10 months of animal studies including primates there has emerged a new drug, NMC-76 which shows promise. In laboratory studies, it has been able to arrest the neurological progression of the disease, however, there has been some question regarding toxicity and side effects of this drug.

Consequently, the team prepared a grant application and submitted it to a federal agency and achieved funding for a three-year project to study the effect and toxicity of NMC-76.

Thirty subjects were selected for this study, twenty of which ranged in age from 15 months to 18 years and the remaining 10 patients were age 19 to 42. Twenty-six of the subjects were black, one was Chicano, and three were white. Nineteen of the subjects were males and 11 were females. All patients were registered in either the pediatric or adult neurological ambulatory facilities of the University Hospital. The principle investigator for this research project was also the Chief of the neurological pediatric facility.

All patients and in the case of minors, their parents, were called together by an associate investigator on the grant (a pediatric neurology fellow) who carefully explained the experiment to them--that the drug NMC-76 had shown promise in laboratory studies and quite possibly could be the first definitive therapy for Garvey's Syndrome thus reducing or eliminating the devastating effects of this crippling and often fatal disease. However, it was further explained that many questions regarding this proposed therapy could not be answered with certainty until human research such as this being proposed was conducted. The subjects were advised that their participation only required the taking of pills on a prescribed schedule, periodic blood samples and follow-up. And, of course, all of this would be at the expense of the University through its grant.

Lastly, they were advised that toxic side effects in the form of skin rash and paresthesias had occurred and obviously unknown side effects could also occur. They were advised that each of them would be carefully monitored for such untoward effects and if any occurred immediate intervention would be carried out either by dosage reduction or complete withdrawal from the project.

Parents and patients were then afforded the opportunity to ask further questions and to sign the University's consent form which had been designed for this research project (that form follows this case).

As the study progressed and the dosage schedules followed, several of the children and two of the adults developed severe bone marrow depression and had to be dropped from the study, however, seven (7) of the patients not showing toxicity showed marked improvement and appeared to have their disease processes arrested. The remainder showed no toxicity or improvement, but at the conclusion of the study, the improved patients were extremely disappointed when informed that their medication was being terminated due to the FDA's failure to approve the drug for continued use.

PATIENT CONSENT FORM

University Hospital
and
Health Services

I, ________________, have voluntarily presented myself or my minor child to participate in a program of clinical investigation described as:

ADMINISTRATION OF NMC-76
FOR GARVEY'S SYNDROME

Further, it has been explained to me that this is an experimental drug and that there are possible unknown risks and side-effects as well as possible benefits to be expected.

Additionally, I have been advised, and I understand that I/or my child can freely withdraw from this study at anytime chosen.

All questions which I have raised have been explained to my satisfication, therefore, I hereby give my informed voluntary consent.

____
Signature of Patient or Legal Guardian

____
Date

WITNESSED BY:

____

____

In this hypothetical case there were numerous abridgements of the rights of the children and adults. From the very onset this grant request in its original form should never have been approved by the University's Human Investigation Review Committee, and if such a committee were properly constituted approval would not likely have been granted. It is axiomatic that such committees have the proper ethnic representation from the group being investigated. Such committees need nonprofessional input to help lessen the conflict of interest which exists when only those with research interests make these determination. A clear example is the fact that the director of the neurologic ambulatory service was also the principle investigator in this supposed research project. Built-in protective mechanisms must exist to preclude the adverse effects of interest conflicts which are, to some degree, inherent in any research design.

When this study was explained to the subjects by one of the associate investigators it should have been conducted on an individual basis with the assistance of a trained social worker and/or someone who could deal with any language barriers. The ghetto tongue most often eludes the university researcher, and vice versa.

Further, during the explanation of this research, patients were mislead when not informed that no previous human studies had been carried out with the drug. Also, any initial studies with this drug should have been restricted to adults.

From the black prespective the most glaring infringement in this hypothetical case is the fact that 26 of the 30 patients enrolled in the study (86%) were black although all ethnic groups within the American population were at equal risk for this disease. This is especially discriminatory when we as a people comprise only 12 percent of the country's total population. Here again, economic factors relate to the method by which health care is obtained by the socioeconomically depressed thereby causing this group to have to bear a disproportionate risk.

Suppose for example during this study it was discovered that the mothers of 3 of the child subjects, who had signed the consent forms, were themselves less than 18 years of age. Should these 3 children be withdrawn from the study even if their mothers wanted them to remain because of the marked improvement they had shown?

Another possible defect in this study was patients were not informed that half of them would not receive NMC-76 but instead a placebo would be prescribed. Even when patients receive prior advice, is it just or fair to knowingly deny a potentially beneficial agent to one group and provide it for another-even if on a chance basis?

Numerous flaws were attendant to the consent form. In addition to not advising that previous studies had not been done in humans, the form also failed to specify that patients' withdrawal from the study would in no way jeopardize their ability to use other university hospital services. The consent form should also have indicated that the informing physician cannot serve as a witness to the signing. Such a witness should be an independent party. Also, such consent forms should allow for the signature of the older minor child participant, perhaps the teenager.

Additionally, it is good practice to provide the research participant with his or her own permanent copy of the consent form for further reference. Also, present on the form should be the investigator's signature attesting to the fact that the conditions setforth in the document have been explained and that no deliberate exclusion of pertinent information has occurrred.

Lastly, but very significantly is the fact that no mention was made in the consent form as to financial responsibility or liability in the event of untoward results occurring from the experiment which would require extensive and or prolonged medical care. Even for those groups of substantial financial means these become extremely important unanswered questions. Surely, the problem is compounded for the black often poor inner city dweller.

The fact that some participants in this hypothetical study developed bone marrow depression and the other participants were not informed of this clearly point outs the need for effective ongoing monitoring of human research. Such monitoring must be required of all human research and structured through the grantee's human investigation review committee--one having appropriate ethnic representation.

Although the case I have presented is a hypothetical one, I am certain that those of you familiar with biomedical/behavioral research rather easily recognize the parallels that are occurring every day. We cannot and should not attempt to proscribe biomedical research--such efforts on our part would not only be unsuccessful but would not serve in our overall best interest. What we must do though is clearly highlight the transgressions that have taken place and thus define and provide mechanisms to effectively prevent their reoccurrences.

In this presentation today, I have examined the issue of human biomedical research from a general perspective and have given special consideration to those issues which have a deeper meaning for black people and their children. I realize that I have raised many questions and answered few. Hopefully, what I have provided is food for thought which will serve as a stimulus for subsequent discussions during this Conference and will allow us to bring forward those concrete recommendations which we seek.

REFERENCES

1. I. Ladimer, "Ethical and Legal Aspects of Medical Research on Human Beings, from Law and Medicine," Journal of Public Law, Vol. 3 (1955), pp. 467-511.

2. H. Foster, "The Poor," in Experiments and Research with Humans: Values in Conflict, pp. 151-153, published by the Academy Forum for the National Academy of Sciences, Washington, D. C., 1975.

3. W. Dubs and D. Johnson, "Study of U. S. Medical School Applicants, 1972-73," Journal of Medical Education, Vol. 49 (1974), pp. 849-869.

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CHILDREN AND THE INSTITUTIONALIZED MENTALLY INFIRM

Crystal A. Kuykendall

INTRODUCTION

In a nation which ostensibly purports equally, life, liberty and the pursuit of happiness for all individuals, it is indeed a tragic perversity that seven million of the nation's children are denied basic "inalienable" human rights enjoyed by the majority of normal Americans. The tragedy is exacerbated by the realization that these individuals are subjugated through institutionalized removal from the mainstream of society not because they are sufficiently deranged but because society chooses to neglect them in an obvious aversion for abnormalities and resulting infirmities. The practice of abrogation as it applies to the right all individuals have to normal growth and development is exemplified in several arguements posited in these pages.

In an analysis of mentally infirmed children who are institutionalized (incarcerated if you will) as a result of their inabilities to conform to societal expectations, reasons for institutionalization will be clarified. Moreover, problems of classifications and labels are analyzed in conjunction with the study of institutionalization as a technique for treatment and healing. Because of a personal contempt for the abridgement of human rights, the writer also endeavors to analyze alternatives available to the mentally infirmed while promulgating recommendations to promote and assure justice and true equity for dejected children as well as more conscionable tomorrows for the privileged majority.

WHAT IS MENTAL INFIRMITY:

Mental infirmity, or mental retardation can best be defined as a condition of inadequately developed intelligence. It has been convincingly argued that mental infirmity is a symptom rather than a syndrome.[1] It is essentially a label used to describe one who deviates from the mental norm indicating usually an irresolute, weak of mind, insecure individual. There are, however, degrees of retardation or actual mental impairment. These degress, for the sake of convenience, can be divided into four levels:[2] 1) Mild. . . Educable mentally retarded children generally fall into this level as they are capable of being brought into a state of self-suffiency as adults. 2) Moderate . . . these children show a rate of mental development which is less than half of that normally expected. They can, however, learn to take care of their personal needs and perform many useful tasks in the home or in a sheltered working situation. 3) Severely . . . these children can also learn self-care, yet because the mental condition has been exacerbated - usually as a result of educational neglect - their potential economic productivity is limited. 4) Profoundly . . . these are generally children who suffer from genetic physical impairments. They respond to training in basic self-care, and they additionally profit from special training in such areas as behavior control, self-protection, language development and physical mobility.

Despite the different levels of mental infirmity the majority of retardates are believed by society to be incapable of managing their personal affairs, unable to control their impulses, basically irresponsible, lacking in human character, ready to engage in physical violence and fights and little interested in the pursuit of education.[3] Attitudes such as these make the adequate treatment of the mentally infirm less imminent. Further, retardates are more likely to land in institutions (hospitals or segregated special education classes) so that society is exonerated from its responsibility in serving its wards with sufficient programs toward total integration into the mainstream as well as equal protection under the law.

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[1] Dorethea Braginsky and Benjamin Braginsky. Hansels and Gretals. New York, Rinehart and Winston, Inc. 1971, p. 13.

[2] For a more detailed description of levels see Charles W. Murdock "Civil Rights and the Mentally Retarded: Some Critical Issues" Notre Dame Lawyer, Vol. 48, No. 1, October 1972, p. 134.

Perhaps the reasons for societal attitudes can be found in the analysis of those who are labeled the mentally infirmed in this country. Michael Katz has stated that schools exist to serve society by tending the characters of otherwise neglected children as they have remained essentially class-biased and racist.[4] Evidence has supported Katz by showing that it is the children of neglected poverty and racial minorities who are victimized most by institutionalization. Indeed, those conscientious Americans who purport an allegiance to humanism should take a long, objective look at the politics of deviancy. According to research by Braginsky, mental retardation is a sociopolitical rather than a psychological construct. It is a myth of a society which refuses to recognize the true nature of its needed social reforms. Indeed, society has as a result successfully camouflaged the politics of diagnosis and incarceration.[5] Generally, anyone who does not fit into the normal school pattern and who is in need of differential or supplemental attention in order to benefit from public instruction is considered exceptional - thereby becoming a candidate for institutionalization. This most often applies to the ethnic poor despite the evidence which shows that language and cultural barriers are not enough to determine innate intelligence.[6] Individual and collective differences are not generally addressed in the basic educational process along racial lines. In assessing programs which define classes of mentally infirmed Laing reached some alarming conclusions about the exclusion of Blacks from the educational process. He felt programs for the emotionally disturbed and socially maladjusted to be no more than euphemisms for aggressive Black male children. He asserted further that schools involved in programs for emotionally disturbed children with subtle connotations of sickness or craziness were apt to co-opt not only special education, but psychiatry, psychology, and social work . . . in a direct fashion while serving to effectively invalidate the cultural experiences of this select group of Black children. Finally, Laing saw the perpetuators of this type of cultural invalidation as the products of a white, racist value system.[7] Society then becomes guilty placing blame on children, consumers of education in this country, rather than the racism which permeates educational institutions. The evidence is exemplary for living on the outskirts of the mainstream when families are marginal. Society responds to their children accordingly.[8]

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[3] Dorethea Braginsky et. al., p. 172.

[4] Michael Katz, Class, Bureaucracy and Schools, Praegers Publishing Co. New York, 1973 p. 12.

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[5] Braginsky, p. 176.

[6] Keith Barry, Models for Mainstreaming, Dimensions Publishing Co. San Rafael, CA 1972, p. 29.

[7] R. Laing, The Politics of Experience, Ballatine Publishing Co. 1969.

It is a fact that potent conditions such as an unloving, unwanting family can transcend any disabilities or abilities of the child.[9] According to Murdock there are many societal pressures operating to induce parents to institutionalize children - ranging from uninformed medical opinion of the "experts' to the parents' own "success" oriented expectations of their children.[10] The case of Wyatt v. Stickney (325 F. Supp. M.D. Ala. 1971) noted that parents may be motivated to ask for institutionalization for a variety of reasons other than the best interests of the child himself (i.e., the interests of other children in the family, mental and physical frustration, economic stress, hostility toward the child stemming from added pressures of caring for him.) Thus, although the child's best interests may well lie in living with his family and in the community, theirs may not lie in keeping him.[11] Welfare agencies, social workers, institutions for the retarded, society in general, as well as the supporting cast of social servants finally complete the process of transformation by labeling and incarcerating the unwanted child. Society's contribution then is not assistance, but the transformation of an unwanted child in need of professional guidance into infirmity. These children become embarrassments to be hidden in order to ease societal guilt. Administrators, teachers and a substantial part of the public have doubted that it was the task of the schools to use curriculum as an instrument of social reform. It has not been felt generally that schools should take responsibility for the fact that an accident of inherited ability or social standing should govern (as they undoubtedly do in part) the pupils' future chances of success in society.

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[8] Braginsky, p. 160.

[9] IBID.

[10] Charles Murdock, p. 140.

[11] Wyatt v. Stickney Amici Briefs, supra note 18, pp. 34-35.

PROBLEMS WITH LABELS AND INSTITUTIONS.

Despite the admission that children who deviate from the norm of societal expectations are labeled in order to facilitate their treatment, there have been the generation of profound arguements which destroy the notion and rationale of both classifications through labeling and resultant institutionalization. We know that classification identifies children who fail to meet societal norms - yet, it has been reasoned that this is because these children pose a threat to the equilibrium of society.[12] According to a Report on Classification of Exceptional Children by the Vanderbilt Institute for Public Policy Studies, classification becomes a mechanism for social control by succeeding in the institutionalization of the values of a cultural majority. Labeling then governs the allocation of resources, regulates access to the opposition and protects the majority from undue anxiety.[13] There is general agreement among researchers that the use of

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[12] Vanderbilt Institute for Public Policy Studies, The Futures of Children: Report on Classification of Exceptional Children, Center for the Study of Families and Children; Vanderbilt University, Nashville, TN June 1975.

[13] IBID. Insight on the continued reliance institutes have on the government are explained. Because they're under financed, the practice of retaining residents who could succeed is continued.

"petrifying" categories is unrevealing, unhelpful, confusing as well as presumptuous."[14] Labeling does indeed make the mentally infirmed easier to identify and count, but not so easy to help. The cost exacted from children society is forced to maintain takes the form of a mental retardate label - which in itself serves to relieve parents and society in this placement into warehouses of "human debris."[15]

The problem of labeling is compounded when one is forced to grapple with the question of whether or not labeling promotes sufficient treatment. Despite the establishment of the Bureau of Education for the Handicapped in the U.S. Office of Education and the creation of commissions to work with classification problems in the executive and legislative branches of the federal government a more flexible classification system has yet to be forthcoming. Old categories have actually been strengthened and new ones added to the detriment of seven million labeled children.[16] What has this done to promote adequate treatment? Very little, on the contrary, the labels succeed most in strengthening social regulations while denying access to opportunity for excluded "undesirables" whose sufficient treatment is too demanding on a society unused to extraordinary efforts for those in need.[17] Research by Braginsky questions the appropriateness of labels to provide adequate treatment by noting the fact that such classification serves only to obfuscate the meaning of the actual disability. The authors point out the fact that in an enriching rewarding milieu even severely brain damaged, genetically impaired or Mongoliod children are able to function normally in many respects.[18] Further, use of negative labels affect the child's self-concept negatively while failing to actually facilitate healing. It has been proven repeatedly that mental retardation, rather than being constant is an immutable condition. It is a reality that emotional disturbances are transitory while external situations influence antisocial behavior. Both conditions will respond to the acquisition of new competencies and the changes in the attitudes and expectations of others. Without question, labels reduce the attention of society to changes in individual development.[19] They are in themselves self-fulfilling prophesies. Teacher expectations for mentally retarded or special education children tend to be lower. Studies have shown that whenever teachers are of the attitude that children are actually below average intelligence, the children tend to regress in their accomplishments.[20] Labels then only serve to single out children who are not necessarily below the norm while dictating societal reaction to them. In the imposition of such a label society then forces future adherence by the child to the label and its meaning. Labels become stigmatizing and debasing as well as inhuman discriminatory attacks on cultural deviants who need only the proper stimuli and environment to reach near normal capacity.

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[14] Braginsky, p. 13.

[15] IBID. p. 162.

[16] Vanderbilt Institute for Public Policy Studies, p. 5.

[17] IBID. p. 10

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[18] Braginsky, p. 179.

[19] Vanderbilt Institute for the Study of Public Policy, p. 14.

[20] George Johnson, "Special Education for Mentally Handicapped - A Paradox." Exceptional Children, Vol. 19, 1962, p. 66. For more information on teacher expectations for special education children see Robert Rosenthal "Teacher Expectancies - Determinants of Pupils' I.Q. Gains.' Psychological Reports, Vol. 19, pp. 115-118, 1966.

The courts have made some efforts to protect individuals from classifications which result from conditions these children have no control while infringing on basic human rights. In the case of Harper v. Virginia Board of Elections, the courts stated, "where fundamental rights and liberties are asserted under the equal protection clauses, classifications which might invade or restrain them must be closely scrutinized and carefully confined."[21] The courts not only made a move to protect fundamental interests by demanding reasons for the classifications, but moved also to protect the interests of those who are not able to effectively protect those personal interests.[22] Yet, the act of labeling children as mentally retardants, mentally handicapped, slow, delinquent, emotionally disturbed, persists. Indeed, labeling is carried to such an extreme that the transitory condition is treated as one of permenance and individuals are carted off - institutionalized - while society continues to negate the need for social reform efforts which can correct the infirmity. This is the consummation of the act of human debasement.

There are 200,000 residents of public institutions - all of them diagnosed as mentally retarded. Thirty percent are children.[23] Most adults are placed in institutions as children. It is not surprising that the longer children are institutionalized and the younger they are when admitted, the greater the negative effects of institutionalization and the more likely these children will meet their label expectations. Despite the admission by many educators that this removal of children from school, home and community through institutionalization is actually of limited value in working out the nature of the problem and giving these children needed treatment so that they can thrive in the communal environment,[24] institutionalization persists. Institutionalization does serve to make residents dependent on their shelter and maladaptive to the outside because of the resultant inability to meet normal life demands.[25]

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[21] Harper v. Virginia Board of Elections 383 U.S. 66370, 1966.

[22] United States v. Carolene Products Co. 304 U.S. 144, 1938. For more insight into this position by the courts, Shapiro v. Thompson 394 U.S. 618 634 (1969) must be looked at as well as Van Dusartz v. Hatfield 334 F. Supp. 870 (D. Minn. 1974).

[23] Vanderbilt Institute for Public Policy Studies, p. 19.

There are several institutional abuses which defeat the purpose for which they were created. Not only is unintentional harm done to residents, but because institutions are shaped by basic drives to accomplish a recognized mission and preserve the perception of that institute by those associated with it, efforts by residents to alter that stability are punished. Patients are faced to play roles which maintain the purpose of the institutions they are confined to. Braginksy maintains institutions degrade retarded children by forcing them to maintain good relationships with all adults encountered[26] something few sophisticated adults could do without becoming sick. The authors contend that if the idea is to treat the mentally infirmed, they should not suffer a deprivation of their essential humanity in a setting which is designed to make it virtually impossible for them to live outside. It should now become clear, institutionalization itself does not solve the problem of individual abnormalities or cultural deviancy. On the contrary, they penalize children for societal neglect, differences and atypical behavior the children are not responsible for.

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[24] Keith Barry, Models for Mainstreaming, p. 14.

[25] Vanderbilt Institute for the Study of Public Policy, p. 19.

[26] IBID.

Why then, in light of the evidence which reveals the dysfunction of publicly supported institutions are they allowed to be maintained? It is well known that most school districts or public institutions are awarded funds on the basis of the number of residents or infirmates in a particular category. Consequently, treatment is often deferred as a method of maintaining the funding source.[28] There are several things which can be done to make certain institutions respond favorably to those profoundly infirmed individuals who really *do* need residential treatment. In deference to necessity, institutions can be improved along three basic lines:

1) *Adequate Screening* - All too often mass screening programs are employed to reach neglected children, yet, in themselves these efforts do not substitute for adequate health care.[29] Screening fosters the use of stigmatizing labels. Therefore, some method of classification should be developed to prevent this consequence. For example, rather than label children "mentally retarded" for failure to meet the norm on measuring instruments which are

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[27] For more discussion see Murdock, p. 155.

[28] See the Vanderbilt Institute *Report on Classification of Exceptional Children*, p. 23 for more insight on how funding locks institutions in.

[29] *IBID*.

inadequate in diagnosing their handicap,[30] children should be identified as requirants of more ingenious teaching methods implemented to help them reach their full potential. Negative labels and screening procedures which identify the below average student also are wrong because they fail to provide insight on the handicaps of average or above children. This may prevent these children from achieving even greater cognitive feats. There should be a constant profile of both the assets and liabilities of these children in order to determine progress, as well as the particular treatment to be used at a given developmental stage.

2) Abuses - Several professional investigations have provided evidence on the physical and mental abuses residents encounter in residential institutions. Conditions such as unclad residents, suffocating odors, physical beatings, overcrowdedness, lack of privacy, ignorance of prescribed medical care by staff, the promotion of parasitism and dehumanization have been identified.[31] In order for institutionalization to be successful, staff must receive training which will instill attitudes of warmth, soliticitude, and overt love for the residents they are employed to service. Further, administrative measures must be tightened so that these deplorable conditions

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[30] See N. Lambert and H. Grossman Problems Determining the Etiology of Learning and Behavior Handicaps. Sacramento, California Department of Education, 1964. ERIC Indix Ed. #22269 as well as Grinspoon and Singer, "Amphetamines in the Treatment of Hyperkinetic Children" Harvard Education Review, 1973, p. 43.

[31] For more information on institutional abuses, see the report of Albert Deutsch to the Philadelphia State Mental Hospital for Mental Diseases, The Shame of the States, p. 42-43, 1948, also Burton Blatt and Fred Kaplan's Christmas in Purgatory - A Photographic Essay on Mental Retardation, p. 22 (1966) as well as the transcripts of the case of Wyatt v. Stickney, Civil No. 3195-N p. 4 (M.D., Ala., March 13, 1972) Both sited in Murdock p. 147-148.

are not allowed to continue.

3) Use of Ecological Systems - In order for children to survive in society, efforts must be exerted to strengthen all of the social systems the child will encounter. Such alternatives as mainstreaming or community mental health centers will be discussed in another section of this paper, yet mention must be made here of the need for institutions to incorporate ecological systems in their treatment programs.

RIGHTS OF THE HANDICAPPED

These recommendations for improvement of residential institutions are made in light of the rights to which institutionalized children are entitled. Other recommendations will follow at the end of this paper. Perhaps the two most critical rights are the rights to humane physical and psychological environment as well as the right to adequate treatment.[32] The right to adequate treatment has been well articulated by Dr. Morton Birnbaum who proposes that the courts move in to protect and ensure that persons labeled as mental retardates actually receive the medical attention which will help them to regain health and consequently liberty more expediously.[33] The first significant judicial development in providing rights to the handicapped came in 1966 with the case of Rouse v. Cameron where a statutory right to treatment was recognized by the District of Columbia Circuit Court by virtue of the 1964 Hospitalization of the Mentally Ill Act.[34] In subsequent court decisions, the District of Columbia broadened the definition of rights by imposing the concept of the "least restrictive alternative" - which says basically that a person in need of treatment for a mental ailment - yet not dangerous - can not be confined in maximum security hospital for the criminally and dangerously insane.[35] Yet, the most far reaching decision came in 1971 with the Wyatt v. Stickney case where the court stated adequate and effective treatment is constitutionally required because absent treatment, the hospital is transformed "into a penitentiary where one could be held indefinitely for no convicted offense...the purpose of involuntary hospitalization for treatment purposes is treatment and not mere custodial care or punishment."[36] Unfortunately, society has not been forced by the courts to abide by the Wyatt decision. Institutions are still synonymous to penitentiaries where infirmities are treated as criminal offenses. Yet, the courts have made the biggest advancement in providing some semblance of equal protection for these dejected children of society. Perhaps this is because the judicial process can be described as "the process of principle" as distinguished from "the art of the possible."[37] There has been a federal effort to provide equal protection for the handicapped. This has come in the form of the Education Amendments of 1974 to Public Law 93-380 which prohibits the denial of equal educational opportunity for all children with specific requirements for the handicapped and the recently passed Public Law 94-142, which authorizes $100 million for 1976 and $200 million for fiscal year 1977 as well as a gradually increasing percentage of the national average pre-pupil expenditure, times the number of handicapped cildren receiving special education each year thereafter. This money is to be earmarked for the excess costs of educating handicapped children with the federal government's share of that cost likely to reach twenty percent by 1982.

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[32] Charles Murdock, p. 146 - Also see transcripts of Townsend v. Treadway (Civil No. 6500 M.D. Tennessee, February 16, 1972) which provided residents the right to be compensated for their labors.

[33] Morton Birnbaum, "The Right to Treatment" Vol. 46 American Bar Association Journal 499, 503 (1960).

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[34] Rouse v. Cameron 373 F. 2d 451 (D.C. Cir. 1966)

[35] See the case of Covington v. Harris, 419 F. 2d 617, 622-25 (D.C. Cer. 1969)

[36] Wyatt v. Stickney 325 F. Supp. 781, 784 (on D. Ala., 1971)

[37] This came from Chief Justice Earl Warren "Notre Dame Law School Civil Rights Lectures" vol. 48 Notre Dame Lawyer, p. 14-16 (1972)

In assessing impacts made to protect the institutionally infirmed, one is reminded of the theory of justice promulgated by John Rawls which states in part that 1) all parties should receive equal rights to the most extensive basic liberties compatible with similar liberties for others and 2) inequalities are to be arranged so that both of them are reasonably expected to be to the advantage of everyone as well as attached to positions and offices open to all.[38]

Several alternatives have been implemented to provide justice for those individuals who are subject to institutionalization as a result of their infirmities. Those alternatives will be discussed briefly in the next section.

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[38] John Rawls, A Theory of Justice, Harvard University Press, Cambridge, Massachusetts (1971) p. 60.

ALTERNATIVES TO INSTITUTIONALIZATION

There can be no denial that those labeled mentally infirmed are indeed different from "normal" children. Yet, this "melting pot" society was founded on a principle of differences. Cultural, racial, ideological, and behavioral differences are to be expected. It is indeed paradoxical then that extreme measures are taken in dealing with the behaviorally different when one considers this country's historical recognition of differences as a condition of liberty. The crux of the matter in relating to differences in cognitive or adaptive abilities then becomes a question of whether or not such differences warrant the exclusion of some or all mentally infirmed children from the basic educational system and the rest of society. In 1971 the Supreme Court ruled illegal the policy of states which allowed them to legislate different treatment to persons placed by statute in the different classes on the basis of criteria wholly unrelated to the objective of that state statute.[39] What this means for the handicapped is that exclusion from public education must be related to the objective of prior state legislation or statute. In the absence of such legislation, classification and exclusion are unreasonable.

The Supreme Court has ruled that children cannot reasonably be expected to succeed in life if denied the opportunity of an education.[40] Since the infirmed are more in need of that opportunity than other members of society, they should, by right be included or mainstreamed into the public school system. Several studies have been undertaken to prove the fact that consistently retarded pupils make as much or more progress in the regular grades as they do in special education classes.[41] It has already been pointed out that special education classes and institutions are composed of behavioral problem children, slow learners, and children who do not speak English as well as the physically disabled and the profoundly infirmed. Exclusion is a method of pushing these children out of society while denying them their lifeline.[42] Certainly, a mainstreaming model would mean the elimination of school exclusion policies for trouble makers,[43] while providing essential growth for all teachers who must meet the challenge of actually teaching the different child. Further "average" students receive personal benefits in the exposure to the less fortunate in heterogenous groupings.

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[39] Reed v. Reed, 404 U.S. 71, pp. 75-76 (1971)

[40] Brown v. Board of Education, 347 U.S. 483 (1954).

The concept of mainstreaming is not a new one in educational philosophy. As early as 1871 Samuel Girdley Howe felt a sure trend in education of exceptional children would be towards integrating them into "common" schools with common classmates in all areas possible.[44] The public schools of the District of Columbia have implemented a model of mainstreaming which seeks first to positively emphasize those variables that have been systematically ignored in traditional special education curriculums. Those variables include spontaneity, problem-solving, ability and creativity, effect of peer groups, social perceptiveness, and especially the cognitive and affective styles which permit the development of extensive non-verbal communication.[45] In this fashion, children who have severe cultural background discrepancies are treated based on a strong supportive program to enhance their strengths and allay any fears and insecurities which may have developed. A study by Braginsky showed that the institutionalized mentally infirmed were no more stupid or inadequate than their non-institutionalized counterparts. Further, these children were able to adopt and use cleverness and resourcefulness to achieve hard-won victories.[46] Does this point out extreme differences?

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[41] Lloyd Dunn, "Special Education for the Mildly Retarded - Is Much of It Justifiable" Exceptional Children, vol. 35, 1968, p. 15. Other studies include C. M. Hoelke Effectiveness of Special Class Placement for Educable Mentally Retarded Children, Lincoln, Nebraska: University of Nebraska, 1966 and Samuel Kirk, Educating Exceptional Children, Houghton-Mifflin Press, Boston, MA 1962. Both authors found segregation of special education children to be neither conducive for learning nor advantageous to regular classroom teachers.

[42] The California Supreme Court in the Serrano v. Priest decision called education the lifeline of the individual and society. 96 California Reporter 487 P. 2d 1241 (1971).

[43] Arnold Buccheimer, Explorations in the Role of Guidance for Youth from the Underclass, Harper and Row, NY 1970, p. 79

[44] Taken from Robert Irwin, As I Saw It, NY American Foundation for the Blind, 1955, p. 128.

One other alternative which has been exemplified to facilitate learning rather than dejection is the concept of early intervention - which affords special attention to behaviorally different children while they are still in kindergarten.[47] Encompassing the idea of the ecological approach is the Community Health Care Center alternative which seeks to avail the infirmed with all resources and techniques of their own home and community in overcoming the malady.

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[45] Interview with D.C. Public Schools Special Education Assistant Director Doris Woolson, November 1974.

[46] Braginsky, p. 135.

[47] Peggy Thomas, "An Ounce of Integration" American Education, Department of Health, Education and Welfare, December 1974.

The Cascade System introduced in 1962 by Maynard Reynolds of the Unviersity of Minnesota is a continuous series of less restrictive alternatives which imply that handicapped children can be transferred into classroom environments. The model is illustrated in Figure 1.[48] All of these alternatives serve to reject the notion that children labeled as infirmities cannot learn and reach their full potential in an average classroom setting. Further, they imply that society must accept its responsibility to protect the rights and fundamental interests of all citizens.

THE CASCADE SYSTEM

Everyday Classroom → Regular Classroom with Consultants
↓
Regular Classroom with Itinerant Teachers
↓
Regular Classroom with Special Resource Room
↓
Part-time Special Class
↓
Full-time Special Class
↓
Special Day School
↓
Residential School
↓
Hospital School
↓
Residential Hospital

Figure 1.

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[48] This model is taken from "One Out of Ten - School Planning for the Handicapped" Report from the Educational Facilities Library of Congress Catalog No. 74-21605.

PERSONAL RECOMMENDATIONS

In a study by Braginsky, ninety-three percent of retardates when asked the question "Why are you here" did not believe they were retarded. Sixty-four percent of these youngsters came from broken homes, another fifty-one percent from families receiving public aid. It is easy to agree with the conclusion of the authors that given certain social-economic conditions, anyone could become an institutionalized mental retardate.[49] Actually, the evidence has shown that of every thirty retarded children, 25 with education are capable of achieving self-sufficiency in the sense of entering the ordinary labor market. Another four, with education, are also capable of achieving self-sufficiency, though in employment in a sheltered environment, and one, with education, is capable of achieving self-care.[50] Considering this evidence, I am inclined to collaborate with Braginsky who states conclusively that the concept of "mental retardation" has led only to enormous expenditures of time, effort and money in a useless search for psychic factor when the real problems exist in society. They feel the concept of mental retardation should, consequently, be discarded.[51]

Clearly, it is society which must accept the blame for vitiated programs for the infirmed which serve only to exacerbate conditions rather than foster healings and returns to normalcy.

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[49] Braginsky, p. 135.

[50] Plaintiff's Memorandum in Support of Their Motion, Pennsylvania Association for the Retarded Child v. Commonwealth of Pennsylvania, 334 F. Supp. 1257 (E. D. Pa. 1971)

[51] Braginsky, p. 176.

Kenneth Clark has noted that the cost of correctional welfare and health services are "intolerably" high in dealing with the consequences of educational inefficiency[52] - implying that society has a moral responsibility to meet the demands of these human casualties in an efficient public education system. Dr. Marvin A. Wirtz, Deputy Commissioner of the U.S. Office of Education Division for the Disadvantaged and Handicapped, Department of Health, Education and Welfare, testified that approximately $178,000 per individual would be saved if children were educated in public institutions for twelve years rather than in life-time institutions. He concluded that "this country could no longer afford to avoid its responsibilites for educating the handicapped - either in financial or moral terms."[53]

It appears to this writer that society seeks to maintain a state of oppression for the culturally and behaviorally different - regardless of the cost. This practice of systematic manipulation of minorities by the system must be abated. In order to promote equal protection, the achievement of full academic potential for all, and an end to the practice of labeling with inadequate measuring instruments, the writer proposes the following:

1) Institutions for the mentally infirmed be used only when the profoundly retarded show they cannot possibly be sustained in a regular academic environment.

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[52] Kenneth Clark, "Alternative Public School Systems," Harvard Educational Review, Harvard University Press, Cambridge, MA 1970, p. 103.

[53] Dr. Marvin Wirtz - 1966 Report of the Governor's Commission to Study the Educational Needs of Handicapped Children in Maryland.

2) In the event that institutions are maintained for the profoundly retarded, they should be improved as follows:

a) Staff should have intensive pre and in-service training so that they're able to satisfy the needs residents have for solicitude, nurturance, love and constant attention as well as adequate medical treatment upon proper diagnosis.

b) Periodic federal inspections be made to insure cleanliness within the actual facility and discontinuance of federal funds if physical abuses are noted.

c) Funds be discontinued if periodic monitoring by the federal or state governments reveal malpractice.

d) Inmates be allowed frequent visits to the home and community so that the environment he will eventually return to is not alien to him.

e) Criterion tests be taken quarterly to determine progress and development so that the resident and community can anticipate a time table for release.

f) Foster homes and parents be provided for residents who come from broken families where they've been tragically neglected.

g) Academic experience be implemented to enhance innate individual ability and maximize cognitive, affective and psychomotor potential.

3) In cases where profound retardation is non-existent, the mildly retarded troublemakers, delinquents, physically handicapped and dejected ethnic minorities should be mainstreamed into regular classrooms with emphasis as follows:

a) Development of individualized curriculum so that problem children are dealt with on the basis of their incommensurable needs within a per pupil budgeting system.[54]

b) Peer teaching, multi-age grouping, team teaching, slip sessions, and criterion referenced tests be employed to facilitate learning while promoting heterogeneous appreciation of differences.

c) Classroom and special subject teachers receive in-service training along with school psychologists and social workers so that extremely disruptive children are not pushed out but given adequate individualized therapeutic treatment.

The actual implementation of these recommendations requires the courage of parents, teachers, administrators, and political leaders. The genius of true leadership is a conviction to do the impossible while exemplifying belief in the far reaching possibilities of all human potential. As John F. Kennedy once noted, "The true measure of a society can be seen in what it does for its members who are least endowed."[55] Surely, few of us would disagree.

CONCLUSIONS

In light of the evidence which proves labeling and resultant institutionalization are not the best techniques for healing, several alternatives and recommendations have been postulated. Those alternatives were:

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[54] For more information, see Crystal Kuykendall for "The Rationale for Incommensurability," unpublished paper presented to the D. C. Board of Education, November, 1974.

[55] Haggerty, Kane and Udall "An Essay on the Legal Rights of the Mentally Retarded" p. 61 - taken from Murdock, p. 171.

1) use of mainstreaming models, 2) early intervention, 3) community health care facilities and 4) where institutionalization is a necessity, improvement of the operation and program of those facilities society can best address needs of those who must be institutionalized through periodic evaluation, adequate testing and monitoring of institutional efforts.

The mentally infirmed need not endure prolonged physical and mental abuse, pedagogical oppression or monstrous abridgements of their human rights at the expense of societal assaugement. Those most committed to justice must join the struggle to correct these inequities through collaborative efforts, involving whole communities - as well as personal avowals to persist until the ultimate victory is satisfactorily achieved.

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(This book was very helpful in providing insight on the dynamics of individualized instruction and how it applies to Special Education)

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(This book provided the best insight on how children have been hurt in segregation programs as well as what has been done in other systems to implement a Mainstreaming Model. This source was treasured for the insight provided.)

Braginsky, Dorethea D. and Benjamin M., Hansels and Gretals: Studies of Children in Institutions for the Mentally Retarded. Holt, Rinehart, and Winston, Inc. 1971.
(This was an excellent study of the social dejection and institutionalization of children for reasons other than retardation.)

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(This book provided interesting reading because the author seemed to have an exceptionally profound understanding of the social problems attributing to the push-out problem. This work was especially beneficial to me because of the three resolutions he recommended to thwart the increase of push-outs.)

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(Carrier presented an excellent portrayal of both special education or exceptional children and disadvantaged youth. He felt their treatment in the educational arena was similar, and suggested individualized instruction and staff development operations as one answer to their problems.)

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(Laing's analysis of how society treats "disadvantaged" Black male youth was outstanding. He added significantly to my understanding of how many attempts to place aggressive youth into classes for the disturbed are racist oriented.)

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Workshops 3 & 4

Resolution and Recommendations
# of the
Workshop on Children

National Minority Conference
on
Human Experimentation
January 8, 1976

PREAMBLE

We call for an immediate halt of experimentation and research of healthy children until such time relatively adequate numbers of minority (sic)* professionals are trained and involved in the process of design, implementation, and monitoring such activities. As a concurrent alternative we recommend that proposed research be submitted to a panel of minority (sic) peer representatives of the researchers and minority (sic) peer representatives of the subject(s) who will monitor the procedures and process of the proposed research. Without the approval of the panel the proposed research would not be approved.

Definition of experimentation

Deliberate attempts at inducing or altering body or mental functions, directly or indirectly in individuals or groups primarily for the advancement of health, science, and human welfare using untested procedures, drugs and sources. The categories of experimentation are: 1) physical; 2) behavioral (psychological and emotional); 3) political, social and cultural; and they are a) controlled and uncontrolled; and b) reported and unreported.

A. STATEMENTS

1. The boundaries between research and treatment - Definition of treatment: The use of approved standards and procedures that are not harmful or experimental.

    a. Maximum safeguards must be provided to prevent abuse and purposeful misrepresentation of research and treatment by providers. Maximum consumer advocacy must be considered.

    b. Individuals, particularly children, should not be denied the best in treatment; and should not be experimented upon as a result of that denial.

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* It is felt that the term minority is an inappropriate term; therefore, negative use of a mind-controlling label to describe people of color.

2. The use of risk/benefit criteria in determining the appropriateness of research involving human subjects. Such criteria must:

    a. Properly address the rights of individuals

    b. Be closely monitored

    c. Be well defined

    d. Maximize benefits to the individual subject

3. Guidelines for the selection of subjects:

    a. Prohibit exploitation/use of any one segment of child population as subjects

    b. Incarcerated children should not be used for experimentation unless they are not disproportionately represented in the numbers proportionate to their minority (sic) representation in the country. In addition, no research on children should be conducted unless that research is designed to specially improve that particular child's condition.

4. There should be no practice of psychosurgery.

5. Informed Consent

    a. No parent or legal representative or guardian shall be permitted to consent to a non-therapeutic experiment unless there is also obtained the informed consent of a third party representing the interests of the child and having no affiliation with the persons or institutions sponsoring or conducting the research. Explanation to child and third party advocate of the risks and benefits of the procedures proposed should be maximum to the point of understanding prior to obtaining informed consent. In addition, the subject and advocate must be informed of the name of the research, the institution, foundation or agency conducting or sponsoring the research, the source of funds and the qualification and prior experience of the researcher.

    b. No child over age 7 shall be the subject of non-therapeutic research without the child's informed consent.

6. Because of lack of concern for human and/or limited knowledge about experimentation;

    Because Research Centers and "Researchers" are removed and/or deliberately walled-off from the community; we recommend the following:

    Whereas research often times affects the local community directly and indirectly, research centers must be closely aligned with the local community.

Whereas the local community must be notified with public announcement 60-90 days prior to any experimentation with any human subject. And be allowed the opportunity to advise and contribute to that particular research project throughout the completion of that research project.

7. Protection of subjects in non-DHEW regulated research must occur by establishing uniform, regulated control at the state level. If states continue to proceed with decentralized research regulations there will be greater discrepancy in the protection and treatment of subjects. The state guidelines should be established and enforced as dictated by the Federal regulations.

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RESPONSIBILITY IN INVESTIGATIONS ON HUMAN SUBJECTS

Excerpt from the Report of the British Medical Research Council

RESPONSIBILITY IN INVESTIGATIONS ON HUMAN SUBJECTS

Reprinted from the Report of the Medical Research Council
for 1962-63 (Cmnd. 2382), Pages 21-25

Responsibility in Investigations on Human Subjects

STATEMENT BY THE MEDICAL RESEARCH COUNCIL

During the last fifty years, medical knowledge has advanced more rapidly than at any other period in its history. New understandings, new treatments, new diagnostic procedures and new methods of prevention have been, and are being, introduced at an ever-increasing rate; and if the benefits that are now becoming possible are to be gained, these developments must continue.

Undoubtedly the new era in medicine upon which we have now entered is largely due to the marriage of the methods of science with the traditional methods of medicine. Until the turn of the century, the advancement of clinical knowledge was in general confined to that which could be gained by observation, and means for the analysis in depth of the phenomena of health and disease were seldom available. Now, however, procedures that can safely, and conscientiously, be applied to both sick and healthy human beings are being devised in profusion, with the result that certainty and understanding in medicine are increasing apace.

Yet these innovations have brought their own problems to the clinical investigator. In the past, the introduction of new treatments or investigations was infrequent and only rarely did they go beyond a marginal variation on established practice. Today, far-ranging new procedures are commonplace and such are their potentialities that their employment is no negligible consideration. As a result, investigators are frequently faced with ethical and sometimes even legal problems of great difficulty. It is in the hope of giving some guidance in this difficult matter that the Medical Research Council issue this statement.

A distinction may legitimately be drawn between procedures undertaken as part of patient-care which are intended to contribute to the benefit of the individual patient, by treatment, prevention or assessment, and those procedures which are undertaken either on patients or on healthy subjects solely for the purpose of contributing to medical knowledge and are not themselves designed to benefit the particular individual on whom they are performed. The former fall within the ambit of patient-care and are governed by the ordinary rules of professional conduct in medicine; the latter fall within the ambit of investigations on volunteers.

Important considerations flow from this distinction.

Procedures contributing to the benefit of the individual

In the case of procedures directly connected with the management of the condition in the particular individual, the relationship is essentially that between doctor and patient. Implicit in this relationship is the willingness on the part of the subject to be guided by the judgment of his medical attendant. Provided, therefore, that the medical attendant is satisfied that there are reasonable grounds for believing that a particular new procedure will contribute to the benefit of that particular patient, either by treatment, prevention or increased understanding of his case, he may assume the patient's consent to the same extent as he would were the procedure entirely established practice. It is axiomatic that no two patients are alike and that the medical attendant must be at liberty to vary his procedures according to his judgment of what is in his patients' best interests. The question of novelty is only relevant to the extent that in reaching a decision to use a novel procedure the doctor, being unable to fortify his judgment by previous experience, must exercise special care. That it is both considerate and prudent to obtain the patient's agreement before using a novel procedure is no more than a requirement of good medical practice.

The second important consideration that follows from this distinction is that it is clearly within the competence of a parent or guardian of a child to give permission for procedures intended to benefit that child when he is not old or intelligent enough to be able himself to give a valid consent.

A category of investigation that has occasionally raised questions in the minds of investigators is that in which a new preventive, such as a vaccine, is tried. Necessarily, preventives are given to people who are not, at the moment, suffering from the relevant illness. But the ethical and legal considerations are the same as those that govern the introduction of a new treatment. The intention is to benefit an individual by protecting him against a future hazard; and it is a matter of professional judgment whether the procedure in question offers a better chance of doing so than previously existing measures.

In general, therefore, the propriety of procedures intended to benefit the individual—whether these are directed to treatment, to prevention or to assessment—are determined by the same considerations as govern the care of patients. At the frontiers of knowledge, however, where not only are many procedures novel but their value in the particular instance may be debatable, it is wise, if any doubt exists, to obtain the opinion of experienced colleagues on the desirability of the projected procedure.

Control subjects in investigations of treatment or prevention

Over recent years, the development of treatment and prevention has been greatly advanced by the method of the controlled clinical trial. Instead of waiting, as in the past, on the slow accumulation of general experience to determine the relative advantages and disadvantages of any particular measure, it is now often possible to put the question to the test under conditions which will not only yield a speedy and more precise answer, but also limit the risk of untoward effects remaining undetected. Such trials are, however, only feasible when it is possible to compare suitable groups of patients and only permissible when there is a genuine doubt within the profession as to which of two treatments or preventive regimes is the better. In these circumstances it is justifiable to give to a proportion of the patients the novel procedure on the understanding that the remainder receive the procedure previously accepted as the best. In the case when no effective treatment has previously been devised then the situation should be fully explained to the participants and their true consent obtained.

Such controlled trials may raise ethical points which may be of some difficulty. In general, the patients participating in them should be told frankly that two different procedures are being assessed and their co-operation invited. Occasionally, however, to do so is contra-indicated. For example, to awaken patients with a possibly fatal illness to the existence of such doubts about effective treatment may not always be in their best interest; or suspicion may have arisen as to whether a particular treatment has any effect apart from suggestion and it may be necessary to introduce a placebo into part of the trial to determine this. Because of these and similar difficulties, it is the firm opinion of the Council that controlled clinical trials should always be planned and supervised by a group of investigators and never by an individual alone. It goes without question that any doctor taking part in such a collective controlled trial is under an obligation to withdraw a patient from the trial, and to institute any treatment he considers necessary, should this, in his personal opinion, be in the better interests of his patient.

Procedures not of direct benefit to the individual

The preceding considerations cover the majority of clinical investigations. There remains, however, a large and important field of investigations on human subjects which aims to provide normal values and their variation so that abnormal values can be recognized. This involves both ill persons and ' healthy ' persons, whether the latter are entirely healthy or patients suffering from a condition that has no relevance to the investigation. In regard to persons with a particular illness, such as metabolic defect, it may be necessary to know the range of abnormality compatible with the activities of normal life or the reaction of such persons to some change in circumstances such as an alteration in diet. Similarly it may be necessary to have a clear understanding of the range of a normal function and its reaction to changes in circumstances in entirely healthy persons. The common feature of this type of investigation is that it is of no direct benefit to the particular individual and that, in consequence, if he is to submit to it he must volunteer in the full sense of the word.

It should be clearly understood that the possibility or probability that a particular investigation will be of benefit to humanity or to posterity would afford no defence in the event of legal proceedings. The individual has rights that the law protects and nobody can infringe those rights for the public good. In investigations of this type it is, therefore, always necessary to ensure that the true consent of the subject is explicitly obtained.

By true consent is meant consent freely given with proper understanding of the nature and consequences of what is proposed. Assumed consent or consent obtained by undue influence is valueless and, in this latter respect, particular care is necessary when the volunteer stands in special relationship to the investigator as in the case of a patient to his doctor, or a student to his teacher.

The need for obtaining evidence of consent in this type of investigation has been generally recognized, but there are some misunderstandings as to what constitutes such evidence. In general, the investigator should obtain the consent himself in the presence of another person. Written consent unaccompanied by other evidence that an explanation has been given, understood and accepted is of little value.

The situation in respect of minors and mentally subnormal or mentally disordered persons is of particular difficulty. In the strict view of the law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and which may carry some risk of harm. Whilst English law does not fix any arbitrary age in this context, it may safely be assumed that the Courts will not regard a child of 12 years or under (or 14 years or under for boys in Scotland) as having the capacity to consent to any procedure which may involve him in an injury. Above this age the reality of any purported consent which may have been obtained is a question of fact and as with an adult the evidence would, if necessary, have to show that irrespective of age the person concerned fully understood the implications to himself of the procedures to which he was consenting.

In the case of those who are mentally subnormal or mentally disordered the reality of the consent given will fall to be judged by similar criteria to those which apply to the making of a will, contracting a marriage or otherwise taking decisions which have legal force as well as moral and social implications. When true consent in this sense cannot be obtained, procedures which are of no direct benefit and which might carry a risk of harm to the subject should not be undertaken.

Even when true consent has been given by a minor or a mentally subnormal or mentally disordered person, considerations of ethics and prudence still require that, if possible, the assent of parents or guardians or relatives, as the case may be, should be obtained.

Investigations that are of no direct benefit to the individual require, therefore, that his true consent to them shall be explicitly obtained. After adequate explanation, the consent of an adult of sound mind and understanding can be relied upon to be true consent. In the case of children and young persons the question whether purported consent was true consent would in each case depend upon facts such as the age, intelligence, situation and character of the subject and the nature of the investigation. When the subject is below the age of 12 years, information requiring the performance of any procedure involving his body would need to be obtained incidentally to and without altering the nature of a procedure intended for his individual benefit.

Professional discipline

All who have been concerned with medical research are aware of the impossibility of formulating any detailed code of rules which will ensure that irreproachability of practice which alone will suffice where investigations on human beings are concerned. The law lays down a minimum code in matters of professional negligence and the doctrine of assault. But this is not enough. Owing to the special relationship of trust that exists between a patient and his doctor, most patients will consent to any proposal that is made. Further, the considerations involved in a novel procedure are nearly always so technical as to prevent their being adequately understood by one who is not himself an expert. It must, therefore, be frankly recognized that, for practical purposes, an inescapable moral responsibility rests with the doctor concerned for determining what investigations are, or are not, proposed to a particular patient or volunteer. Nevertheless, moral codes are formulated by man and if, in the ever-changing circumstances of medical advance, their relevance is to be maintained, it is to the profession itself that we must look, and in particular to the heads of departments, the specialized Societies and the editors of medical and scientific journals.

In the opinion of the Council, the head of a department where investigations on human subjects take place has an inescapable responsibility for ensuring that practice by those under his direction is irreproachable.

In the same way the Council feel that, as a matter of policy, bodies like themselves that support medical research should do everything in their power to ensure that the practice of all workers whom they support shall be unexceptionable and known to be so.

So specialized has medical knowledge now become that the profession in general can rarely deal adequately with individual problems. In regard to any particular type of investigation, only a small group of experienced men who have specialized in this branch of knowledge are likely to be competent to pass an opinion on the justification for undertaking any particular procedure. But in every branch of medicine specialized scientific societies exist. It is upon these that the profession in general must mainly rely for the creation and maintenance of that body of precedents which shall guide individual investigators in case of doubt, and for the critical discussion of the communications presented to them on which the formation of the necessary climate of opinion depends.

Finally, it is the Council's opinion that any account of investigations on human subjects should make clear that the appropriate requirements have been fulfilled and, further, that no paper should be accepted for publication if there are any doubts that such is the case.

The progress of medical knowledge has depended, and will continue to depend, in no small measure upon the confidence which the public has in those who carry out investigations on human subjects, be these healthy or sick. Only in so far as it is known that such investigations are submitted to the highest ethical scrutiny and self-discipline will this confidence be maintained. Mistaken, or misunderstood, investigations could do incalculable harm to medical progress. It is our collective duty as a profession to see that this does not happen and so to continue to deserve the confidence that we now enjoy.

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Society for Research in Child Development

ETHICAL STANDARDS FOR RESEARCH WITH CHILDREN

Leon Yarrow, President of SRCD, presents the following report prepared by the Committee on Ethics in Research with Children.

Children as research subjects present ethical problems for the investigator different from those presented by adult subjects. Not only are children often viewed as more vulnerable to stress but, having less knowledge and experience, they are less able to evaluate what participation in research may mean. Consent of the parent for the study of his child, moreover, must be obtained in addition to the child's consent. These are some of the major differences between research with children and research with adults.

1. No matter how young the child, he has rights that supersede the rights of the investigator. The investigator should measure each operation he proposes in terms of the child's rights, and before proceeding he should obtain the approval of a committee of peers. Institutional peer review committees should be established in any setting where children are the subjects of the study.

2. The final responsibility to establish and maintain ethical practices in research remains with the individual investigator. He is also responsible for the ethical practices of collaborators, assistants, students, and employees, all of whom, however, incur parallel obligations.

3. Any deviation from the following principles demands that the investigator seek consultation on the ethical issues in order to protect the rights of the research participants.

4. The investigator should inform the child of all features of the research that may affect his willingness to participate and he should answer the child's questions in terms appropriate to the child's comprehension.

5. The investigator should respect the child's freedom to choose to participate in research or not, as well as to discontinue participation at any time. The greater the power of the investigator with respect to the participant, the greater is the obligation to protect the child's freedom.

6. The informed consent of parents or of those who act _in loco parentis_ (e.g., teachers, superintendents of institutions) similarly should be obtained, preferably in writing. Informed consent requires that the parent or other responsible adult be told all features of the research that may affect his willingness to allow the child to participate. This information should include the profession and institutional affiliation of the investigator. Not only should the right of the responsible adult to refuse consent be respected, but he should be given the opportunity to refuse without penalty.

7. The informed consent of any person whose interaction with the child is the subject of the study should also be obtained. As with the child and responsible adult, informed consent requires that the person be informed of all features of the research that may affect his willingness to particpate; his questions should be answered; and he should be free to choose to participate or not, and to discontinue participation at any time.

8. From the beginning of each research investigation, there should be a clear agreement between the investigator and the research participant that defines the responsibilities of each. The investigator has the obligation to honor all promises and commitments of the agreement.

9. The investigator uses no research operation that may harm the child either physically or psychologically. Psychological harm, to be sure, is difficult to define; nevertheless, its definition remains the responsibility of the investigator. When the investigator is in doubt about the possible harmful effects of the research operations, he seeks consultation from others. When harm seems possible, he is obligated to find other means of obtaining the information or to abandon the research.

10. Although we accept the ethical ideal of full disclosure of information, a particular study may necessitate concealment or deception. Whenever concealment or deception is thought to be essential to the conduct of the study, the investigator should satisfy a committee of his peers that his judgment is correct. If concealment or deception is practiced, adequate measures should be taken after the study to ensure the participant's understanding of the reasons for the concealment or deception.

11. The investigator should keep in confidence all information obtained about research participants. The participant's identity should be concealed in written and verbal reports of the results, as well as in informal discussions with students and colleagues. When a possibility exists that others may gain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participants as a part of the procedure for obtaining informed consent.

12. To gain access to institutional records the investigator should obtain permission from responsible individuals or authorities in charge of records. He should preserve the anonymity of the information and extract no information other than that for which permission was obtained. It is the investigator's responsibility to insure that these authorities do, in fact, have the confidence of the subject and that they bear some degree of responsibility in giving such permission.

13. Immediately after the data are collected, the investigator should clarify for the research participant any misconceptions that may have arisen. The investigator also recognizes a duty to report general findings to participants in terms appropriate to their understanding. Where scientific or humane values may justify withholding information, every effort should be made so that withholding the information has no damaging consequences for the participant.

14. Because the investigator's words may carry unintended weight with parents and children, caution should be exercised in reporting results, making evaluative statements, or giving advice.

15. When, in the course of research, information comes to the investigator's attention that may seriously affect the child's well-being, the investigator has a responsibility to discuss the information with those expert in the field in order that the parents may arrange the necessary assistance for their child.

16. When research procedures may result in undesirable consequences for the participant that were previously unforeseen, the investigator should employ appropriate measures to correct these consequences, and should consider redesigning the procedures.

17. The investigator should be mindful of the social, political, and human implications of his research and should be especially careful in the presentation of his findings. This standard, however, in no way denies the investigator the right to pursue any area of research or the right to observe proper standards of scientific reporting.

18. When an experimental treatment under investigation is believed to be of benefit to children, control groups should be offered other beneficial alternative treatments, if available, instead of no treatment.

19. Teachers of courses related to children should demonstrate their concern for the rights of research participants by presenting these ethical standards to their students so that from the outset of training the participants' rights are regarded as important as substantive findings and experimental design.

20. Every investigator has a responsibility to maintain not only his own ethical standards but also those of his colleagues.

21. Editors of journals reporting investigations of children have certain responsibilities to the authors of studies they review: they should provide space where necessary for the investigator to justify his procedures and to report the precautions he has taken. When the procedures seem questionable, editors should ask for such information.

9

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PROTECTION OF HUMAN SUBJECTS, POLICIES AND PROCEDURES

Federal Register, Volume 38, No. 221, Part II
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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

■

NATIONAL INSTITUTES OF HEALTH

Protection of Human Subjects

Policies and Procedures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

PROTECTION OF HUMAN SUBJECTS

Policies and Procedures

In the Federal Register of October 9, 1973 (38 FR 27882 et seq.), the Secretary of Health, Education, and Welfare issued a notice of proposed rulemaking concerning the protection of human subjects and mentioned that DHEW through the National Institutes of Health, had appointed a special study group to review and recommend policies and special procedures for the protection of children, prisoners, and the institutionalized mentally infirm in research, development, and demonstration activities. The report of this study group has been completed in *draft* form and reviewed by the Director, NIH.

There may well be elements in the recommendations which will provoke debate and controversy. We recognize that public consideration and comment are vital to the development of our final recommendations to the Secretary and are inviting such comment now even though the materials are still pending final review and completion. The product of our effort after considering public comment will be transmitted to the Assistant Secretary for Health, HEW to recommend to the Secretary, HEW that it appear again in the Federal Register as proposed rulemaking for further public comment. Such a procedure is consistent with long established DHEW policy for permitting extensive public opportunity to affect the promulgation of DHEW regulations.

It must be clearly understood by the reader that the material that follows is *not* proposed rulemaking in the technical sense, and is not presented as Departmental, Public Health Service, or NIH policy. Rather it is a draft working document on which early public comment and participation is invited.

Please address any comments on these draft policies and procedures to the Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. All comments should be received by January 4, 1974.

Additional copies of this notice are available from the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014.

Dated: November 6, 1973.

Robert S. Stone,
Director,
National Institutes of Health.

Research, Development, and Demonstration Activities: Limitations of Informed Consent

SPECIAL POLICY CONSIDERATIONS

Summary

November 5, 1973.

The mission of the Department of Health, Education, and Welfare includes the improvement of the health of the Nation's people through research, development, and demonstration activities which at times involve human subjects. Thus, policies and procedures are required for the protection of subjects on whose participation these activities depend.

Informed consent is the keystone of the protection of human subjects involved in research, development, and demonstration activities. Certain categories of persons have limited capacity to concent to their involvement in such activities. Therefore, as a supplement to DHEW policies, special protections are proposed for *children, prisoners,* and the *mentally infirm* who are to be involved in research, development, and demonstration activities.

Agency "Ethical Review Boards" are to be established to provide rigorous review of the ethical issues in research, development, and demonstration activities involving human subjects, in order to make judgments regarding societal acceptability in relation to scientific value. "Protection Committees" are to be established by the applicant to provide "supplementary judgment" concerning the reasonableness and validity of the consent given by, or on behalf of, subjects. The intent of this policy is that institutions which apply for DHEW funds or submit research in fulfillment of DHEW regulations, must be in compliance with these special protections, whether or not particular research, development, or demonstration activities are Federally activities.

1. *Children.* If the health of children is to be improved, research activities involving their participation is often essential. Limitation of their capacity to give informed consent, however, requires that certain protections be provided to assure that scientific importance is weighed against other social values in determining acceptable risk to children. Therefore, research, development, and demonstration activities which involve risk to children who participate must:

a. Include a mechanism for obtaining the consent of children who are 7 years of age or older;

b. Include the applicant's proposal for use of a Protection Committee which is appropriate to the nature of the activity;

c. Be reviewed and approved, in conformity with present DHEW policy, by an Organizational Review Committee; and

d. Be reviewed by the appropriate agency Primary Review Committee, the Ethical Review Board, and the appropriate secondary review group.

2. *Special categories.*—a. *The Abortus.* No research, development, or demonstration activity involving the non-viable abortus shall be conducted which:

1. Will prolong heart beat and respiration artificially solely for the purpose of research;

2. Will of itself terminate heart beat and respiration;

3. Has not been reviewed by the agency Ethical Review Board; and

4. Has not been consented to by the pregnant woman with participation of a Protection Committee.

(An abortus having the capacity to sustain heart beat and respiration is in fact a premature infant, and all regulations governing research on children apply.)

b. *The fetus in utero.* No research involving pregnant women shall be conducted unless:

1. Primary Review Groups assure that the activity is not likely to harm the fetus;

2. the agency Ethical Review Board has reviewed the activity;

3. a Protection Committee is operating in a manner approved by the agency; and

4. the consent of both prospective legal parents has been obtained, when reasonably possible.

c. *Products of in vitro fertilization.* No research involving implantation of human ova which have been fertilised *in vitro* shall be approved until the safety of the technique has been demonstrated as far as possible in sub-human primates, and the responsibilities of the donor and recipient "parents" and of research institutions and personnel have been established. Therefore, no such research may be conducted without review of the Ethical Review Board and of a Protection Committee.

3. *Prisoners.* Research, development, and demonstration activities involving human subjects often require the participation of normal volunteers. Prisoners may be especially suitable subjects for such studies, although there are problems concerning the voluntariness of the consent of normal volunteers who are confined in institutions. Certain protections are required to compensate for the diminished autonomy of prisoners in giving voluntary consent. Research, development, and demonstration activities involving prisoners must:

a. Include the applicant's proposal for use of a Protection Committee which is appropriate to the nature of the activity;

b. Be reviewed and approved by an Organizational Review Committee which may already exist in compliance with present DHEW policy or which must be appointed in a manner approved by the appropriate DHEW agency;

c. Be reviewed by the agency Primary Review Committee, and

d. Be conducted in an institution which is accredited by the Secretary of Health, Education, and Welfare.

4. *The mentally infirm.* Insofar as the institutionalized mentally infirm might lack either the competency or the autonomy (or both) to give informed consent, their participation in research requires additional protection:

a. Research, development and demonstration activities involving the mentally infirm will be limited to investigations concerning (1) diagnosis, etiology, prevention, or treatment of the disability from which they suffer, or (2) aspects of institutional life, *per se*, or (3) information which can be obtained only from such subjects.

All research, development and demonstration activities involving such persons must:

1. Include the applicant's assurance that the study can be accomplished *only*

with the participation of the mentally infirm;

2. Include the applicant's proposal for use of a Protection Committee which is appropriate to the activity; and

3. Be reviewed and approved by an Organizational Review Committee, in conformity with present DHEW policy.

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INTRODUCTION

The mission of the Department of Health, Education, and Welfare includes the improvement of the health of the Nation's people through biomedical research. This mission requires the establishment of policy and procedures for the protection of subjects on whose participation that research depends. In DHEW policy, as well as in ethical codes pertaining to research in human subjects, the keystone of protection is informed consent.

An uncoerced person of adult years and sound mind may consent to the application of standard medical procedures in the case of illness, and when fully and properly informed, may legally and ethically consent to accept the risks of participating in research activities. Parents and legal guardians have authority to consent on behalf of their child or ward to established therapeutic procedures when the child is suffering from an illness, even though the treatment might involve some risk.

There is no firm legal basis, however, for parental or guardian consent to participation in research on behalf of subjects who are incompetent, by virtue of age or mental state, to understand the information provided and to formulate the judgments on which valid consent must depend. In addition, current policies for clinical research afford such subjects inadequate protection. Nevertheless, to proscribe research on all such subjects, simply because existing protections are inadequate, would be to deny them potential benefits, and is, therefore, inequitable. Knowledge of some diseases and therapies can be obtained only from those subjects (such as children) who suffer from the disease or who will be receiving the therapy. Their participation in research is necessary to progress in those fields of medicine. When such subjects participate in research, they need more protection than is provided by present policy.

There are other individuals who might be able to comprehend the nature of the research, but who are involuntarily confined in institutions. Insofar as incarceration might diminish their freedom of choice, and thus limit the degree to which informed consent can be freely given, they too need additional protection. Current policies do not recognize the limitations on voluntariness of consent which may emanate from incarceration.

This addition to existing policy is offered as a means of providing adequate protection to subjects who, for one reason or another, have a limited ability to give truly informed and fully autonomous consent to participate in research. The aim is to set standards which are both comprehensive and equitable, in order to provide protection and, to the extent consistent with such protection, maintain an environment in which clinical research may continue to thrive.

1. *Definitions.* For purposes of this policy:

A. *Subject at risk* means any individual who might be exposed to the possibility of harm (physical, psychological, sociological, or other) as a consequence of participation as a subject in any research, development or demonstration activity (hereinafter called "activity") which goes beyond the application of established and accepted methods necessary to meet his needs.

B. *Clinical research* means an investigation involving the biological, behavioral, or psychological study of a person, his body or his surroundings. This includes but is not limited to any medical or surgical procedure, any withdrawal or removal of body tissue or fluid, any administration of a chemical substance, any deviation from normal diet or daily regimen, and any manipulation or oberservation of bodily processes, behavior or environment. Clinical research comprises four categories of activity:

1. Studies which conform to established and accepted medical practice with respect to diagnosis or treatment of an illness.

2. Studies which represent a deviation from accepted practice, but which are specifically aimed at improved diagnosis, prevention, or treatment of a specific illness in a patient.

3. Studies which are related to a patient's disease but from which he or she will not necessarily receive any direct benefit.

4. Investigative, non-therapeutic research in which there is no intent or expectation of treating an illness from which the patient is suffering, or in which the subject is a "normal control" who is not suffering from an illness but who volunteers to participate for the potential benefit of others.

It is important to emphasize that "non-therapeutic" is not to be understood as meaning "harmful." Understanding of normal processes is essential; it is the prerequisite, in many instances, to recognition of those deviations from normal which define disease. Important knowledge can be gained through such studies of normal processes. Although such research might not in any way benefit the subjects from whom the data are obtained, neither does it necessarily harm them.

Patients participating in studies identified in paragraph B-1, above, are not considered to be at special risk by virtue of participating in research activities, and this policy statement offers no special protection to them. When patients or subjects are involved in procedures identified in paragraphs B2, B3, and E4, they are considered to be "at risk," and the special policy and procedures set forth in this document pertain. Excluded from this definition are studies in which the risk is negligible, such as research requiring only, for example, the recording of height and weight, collecting excreta, or analysing hair, deciduous teeth, or nail clippings. Some studies which appear to involve negligible physical risk might, however, have psychological, sociological or legal implications which are significant. In that event, the subjects are in fact "at risk," and appropriate procedures described in this document shall be applied.

C. *Children* are individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the proposed research is to be conducted.

D. *Pregnancy* encompasses the period of time from implantation until delivery. All women during the child bearing years should be considered at risk of pregnancy; hence, prudence requires definitive exclusion of pregnancy when women in this period of life are subjects for experimentation which might affect the fetus.

E. *Fetus* means the product of conception from the time of implantation to the time of delivery from the uterus.

F. *Abortus* means a fetus when it is expelled whole, whether spontaneously or as a result of medical or surgical intervention undertaken with the intention of terminating a pregnancy, prior to viability. This definition, for the purpose of this policy, excludes the placenta, fetal material which is macerated at the time of explusion, a dead fetus, and isolated fetal tissue or organs excised from a dead fetus.

G. *Viability of the fetus*, means the ability of the fetus, after either a spontaneous delivery or an abortion, to survive to the point of independently maintaining vital functions; such a "viable" fetus is a premature infant. Determination of viability entails a subjective and objective judgment by the physician attending labor or examining the product of conception, and must be made by a physician other than the investigator wishing to use fetal tissue in research. In general, and all other circumstances notwithstanding, a beating heart is not sufficient evidence of viability. At least one additional necessary condition is the possibility that the lungs can be inflated. Without this precondition, no currently available mechanisms to initiate or maintain respiration can sustain life; and in this case, though the heart is beating, the fetus or abortus is in fact non-viable.

H. *In vitro fertilization* is any fertilization of human ova which occurs outside the body of the female, either through admixture of donor sperm and ova or by any other means.

I. *Prisoner* is any individual involuntarily confined in a penal institution. The term in intended to encompass individuals sentenced to such an institution under a criminal or civil statute, or individuals detained by virtue of statutes which provide alternatives to criminal prosecution.

J. *Mentally infirm* includes the mentally ill, the mentally retarded, the emotionally disturbed, the psychotic, the senile, and others with impairments of a similar nature, residing as patients in an institution, regardless of whether or not the individual has been determined to be legally incompetent.

K. *Informed consent* has two elements: comprehension of adequate information and autonomy of consent. Consent is a continuing process. The person giving consent must be informed fully of the nature and purpose of the research and of the procedures to be used, including identification of those procedures which are experimental, the possible attendant short or long term risks and discomforts, the anticipated benefits to himself and/or others, any alternative methods of treatment, expected duration of the study, and of his or her freedom to ask any questions and to withdraw at any time, should the person wish to do so. There must also be written evidence of the process used for obtaining informed consent, including grounds for belief that the subject has understood the information given and has sufficient maturity and mental capacity to make such choices and formulate the requisite judgment to consent. In addition, the person must have sufficient autonomy to choose, without duress, whether or not to participate. Both the comprehension of information and the autonomy of consent are necessary elements; to the extent that either of these is in doubt, the adequacy of informed consent may be in doubt.

L. *Supplementary judgment* is the judgment made by others to assent, or to refuse to assent, to procedures for which the subject cannot give adequate consent on his or her own behalf. For the purposes of this document, supplementary judgment will refer to judgments made by local committees in addition to the subject's consent (when possible) and that of the parents or legal guardian (where applicable), as to whether or not a subject may participate in clinical research. This supplementary judgment is to be confirmed by the signature of the Chairman of the Protection Committee on the consent form. In accordance with the procedures approved by the agency for the Protection Committee, the Chairman's signature may be affixed on a standard consent form, or may need to be withheld until the Committee approves the participation of the individual subject.

II. *General policy considerations*. In general, clinical research, like medical practice, entails some risk to the subjects. When the potential subject is unable fully to comprehend the risks which might be involved, or to make the judgment essential to consent regarding the assumption of those risks, current guidelines suggest obtaining the consent of the parents or legal representative.

Whereas it is clear by law that consent of a parent or legal representative is valid for established and generally accepted therapeutic procedures performed on a child or an incompetent adult, it is far from clear that it is adequate for research procedures. In practice, parental or guardian consent generally has been accepted as adequate for therapeutic research, although the issue has not been definitively resolved in the courts. When research might expose a subject to risk without defined therapeutic benefit or other positive effect on that subject's well-being, parental or guardian consent appears to be insufficient.

In the case of prisoners, confinement imposes limitations on freedom of choice which brings into question their ability to give voluntary consent. A prisoner's ability to give consent may be restricted by overt or potential coercion, or by the loss of personal autonomy generally considered to result from incarceration itself. Therefore, additional protection must be afforded this group even though an individual's competency to understand what is involved might not be in doubt.

The institutionalized mentally infirm are doubly limited: as with children, they might not be competent to make informed judgments, and, as with prisoners, they are confined under conditions which limit their civil freedom and autonomy. Therefore, their participation in research requires special protections.

The law is not clear on these issues. Even if the law were clear, however, ethical questions would remain; specifically, whether, and under what conditions research involving these subject groups may proceed. Resolution of these ethical questions requires judgments concerning both the ethics of conducting a particular research project, and the adequacy of procedures for protecting the individual subjects who will be asked to participate. The intention of this policy is to broaden the scope of review, preclude or resolve conflicts of interest, and invoke social as well as scientific judgments to protect potential subjects who might have diminished capacity to consent.

The proposed mechanism for protecting subjects with limited ability to give informed consent culminates in a form of supplementary judgment, which is to be supportive and protective of the subject's best interests and wishes, to the extent that he or she is capable of formulating and expressing a judgment. In the case of children and the mentally infirm, it will supplement their judgment and that of their parents or guardians. In the case of competent individuals who have restricted autonomy, it will support and protect their wishes. Through this mechanism, these subjects will be protected as fully as possible by community review; however, the nature of some research procedures might be such that, in addition, court review ultimately will be required.

III. *Participation of children in research*—A. *Policy considerations*. Children have generally been considered inappropriate subjects for many research activities because of their inability to give informed consent. There are circumstances, however, which not only justify, but even require their participation. Children do differ from adults in their physiologic responses, both to drugs and to disease; if the health of children is to be improved, it is necessary to know the nature and extent of these differences, and to have a full understanding of normal patterns of growth and development, metabolism, and biochemistry in the perinatal, infant, early childhood, pubertal and adolescent stages of development. Studies of normal physiology and behavior can also provide significant benefit to children suffering from disease; children are the only subjects from whom these data can be obtained. Furthermore, there are diseases which cannot be induced in laboratory animals, and occur only rarely, if at all, in human adults. In such cases, children are the only subjects in whom the disease process and possible modes of therapy can be studied.

The Kefauver-Harris Act[1] requires that drugs be tested for safety, efficacy and dosage in children and pregnant women before being approved for use to treat illness in such patients. Food and Drug Administration (FDA) approval for the use of a new drug depends upon submission of proposed labeling for a new drug, which must include "adequate directions for use" and "adequate warnings" as to unapproved uses.[2] Acceptance of a new drug rests on the adequacy of the research reports submitted with the application to support the proposed labeling.[3] Thus, in order for a drug to be distributed in interstate commerce for use in children or pregnant women, sufficient testing must have taken place in children or pregnant women to substantiate claims on the label regarding safety, efficacy, and dosage for those groups. If the safe and efficacious dosage for children and pregnant women has not been determined, the label must so state. Thus, participation of children in drug research might be the only means of meeting licensing requirements for new drugs for use in children, just as studies in pregnant women might be the only means of meeting licensing requirements for new drugs for use in that class of patients.

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[1] Federal Food, Drug, and Cosmetic Act, 1962 (FDC Act), 21 U.S.C. Sec. 301 et. seq.

[2] FDC Act Sec. 502(f), 21 U.S.C. Sec. 352(f).

When the risk of a proposed study is generally considered not significant, and the potential benefit is explicit, the ethical issues need not preclude the participation of children in biomedical research. However, the progression from innocuous to noxious, in terms of risk, is often subtle. Therefore, additional review procedures are necessary for research activities which expose children to risk, in order to provide sharp scrutiny, vigorous review, and stringent procedural safeguards for all subjects of such research.

Judgments concerning the ethical propriety of research depend partly upon the scientific assessment of the potential risks and benefits. Risk has several important elements: severity, probability, frequency, and the timing of possible adverse effects. While it might not always be easy to distinguish these elements, they must be evaluated in the assessment of risk, and in the determination of the acceptable limits of specific risk for an anticipated benefit. The first judgment to be made is whether it is possible to assess the risk. If studies in animals or adults do not provide sufficient information to assess these elements of risk, then the research should not be conducted on children. If the risks can be determined from studies in animal and adult human populations, application to children may be considered.

In addition to results from investigations on animals and adult subjects, there are unknowns which must be considered in the weighing of risk to children. These include: (1) differences in physiologic or psychologic response from adult patterns; (2) delayed expression of injury (for example, until puberty); (3) effects on developing organs (especially the central nervous system); (4) degree of interference with normal routine required by the study; and (5) possibility of misuse of data by institution or school personnel.

Once the severity and probability of risks in a particular study have been identified, a second judgment must be made: given potential benefits of described dimensions, what are the acceptable limits of risk to which children ethically may be subjected? Value judgments which must be weighed here transcend scientific issues and suggest that the decision requires interaction among individuals in society with diverse training and perspectives. Further, given the complexity of the issues and the opportunity for conflict among the interests of several parties (the child, the parents or guardian, the attending physician, and the research personnel), decisions regarding participation of individual subjects in research activities involving children should not rest solely with persons directly involved in the research.

In order to provide both impartial ethical review of projects and maximum protection of individual subjects, two procedures are proposed in addition to those currently required: review by an Ethical Review Board at the sponsoring DHEW agency, and participation by a Protection Committee at the institution in which the research is to be conducted. Both groups will provide community involvement in decisions and attempt to balance scientific value and societal acceptability of proposed research involving children.

B. *Ethical Review Board: Ethical review of projects.* Each DHEW agency shall appoint an Ethical Review Board to provide rigorous review of ethical issues in research involving human subjects by people whose interests are not solely those of the scientific community. Its functions will include:

1. Advising the agency on ethical issues including review of questions of policy, and development of guidelines and procedures;

2. Fostering inter-agency coherence through cognizance of the policies and procedures of other agencies;

3. Reviewing specific proposals or classes of proposals submitted to the Board by the agency. These will include proposals stipulated herein as requiring review by the Board, as well as proposals submitted on an *ad hoc* basis by agency staff. In addition, the Board may recommend that certain additional classes of research be reviewed.

The acceptability of a research project rests on questions of scientific merit as well as on questions of ethics. The agency Primary Review Committees are responsible for evaluating scientific merit and experimental design. The Ethical Review Board will be concerned with ethical issues and questions of societal acceptability in relation to scientific value. In reaching its determination of acceptability, the Board will rely upon the Primary Review Committees for judgments on scientific merit and design, existence of prerequisite animal and adult human studies, estimated risks and benefits (taking into account the competence and experience of investigators and the adequacy of their resources), and scientific importance. It will review proposals received from these Primary Review Committees.

An investigator proposing research activities which expose children to risk must document, as part of the application for support, that the information to be gained can be obtained in no other way. The investigator must also stipulate either that the risk to the subjects will be insignificant, or that although some risk exists, the potential benefit is significant and far outweighs that risk. In no case will research activities be approved which entail substantial risk, except in the case of clearly therapeutic procedures in which the benefit to the patient significantly outweighs the possible harm. The Ethical Review Board shall review all proposals approved by Primary Review Committees involving children in research activities, except when the Primary Review Committees determine that the subjects are not at risk.

In addition to reviewing ethical issues, the Board will review procedures proposed in the research application to be employed by the institution's Protection Committee (see below), and may suggest modifications of these procedures. The Board's recommendation may vary from a general concurrence with the proposal, as submitted by the investigator, to a recommendation that each parental and subject consent must be obtained with the concurrence of the full Protection Committee. Any specific recommendations for procedures to be followed by the Protection Committee will be included in the report of the Ethical Review Board which will be forwarded to the National Advisory Councils or other secondary review groups of the agency. Appropriate information will be provided by the agency to assist the Protection Committee.

Inasmuch as the articulation of decisions might clarify both the objectives and the assumptions on which they are based, records of testimony and deliberations, as well as final decisions, should be maintained pursuant to existing regulations. Such records will serve additionally as the basis for public accountability and will facilitate the review of any decision, should such action be requested.

Members of the Board, which shall number 15, shall be drawn from the general public, and shall include, for example, research scientists (including social scientists), physicians, lawyers, clergy, or ethicists, and other representatives of the public, none of whom shall be employees of the agency establishing the Board. Appointments shall be made by the agency, which will establish the terms of office and other administrative procedures of the Board. No more than ⅓ of the members of the Board may be actively engaged in research, development, or demonstration activities involving human subjects.

C. *Protection Committee: Protection of individual subjects.* The determination that it is justifiable to conduct a particular investigation in children, however, does not mean that all children are equally appropriate subjects for inclusion in that research. Numerous considerations might affect the proper choice of subjects. Therefore, the sponsoring institution shall designate a Protection Committee to oversee: (1) the process of selection of subjects who may be included in the project; (2) the monitoring of their continued willingness to participate in the research; and (3) the design of procedures to permit intervention on behalf of the subject, should that become necessary. This Committee should consider the reasonableness and validity of the consent of the child participants (see below) as well as that of the parents, and should assure that the issue of risk and discomfort has been fully and fairly disclosed to parents and subjects. The procedure employed by the institution to achieve these goals will vary; the latitude for such procedures will be great since it will be related in part to the issue of risk. Investigators proposing research involving children shall include a description of their planned use of the Protection Committee in their research proposal; the proposed use of this Committee will be considered an integral part of the research proposal under review by the agency. Relevant information arising in the review process, including information about safety, risk, efficacy, and protection procedures, will be provided to the Protection Committee by the agency supporting the research.

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[3] FDC Act Sec. 505 (b), (d), 21 U.S.C. Sec. 355 (b), (d).

One member of the Committee shall be designated a representative for the project to whom any participant (or parent of a participant) may go to discuss questions or reservations concerning the child's continued participation in the project.

The signature on the consent form of the Chairman of the Protection Committee, when all the stipulations and conditions identified above have been met, will constitute, for DHEW, *supplementary judgment* on behalf of the child subject.

The institution's Protection Committee shall be comprised of at least 5 members so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved in the research, and to represent the community from which the subject population is to be drawn. The Committee should include members of both sexes. No more than two of the members may be employees of the institution sponsoring or conducting the research. The Protection Committee may operate as a subcommittee of the Organizational Review Committee. The composition of the Committee must be approved by the awarding agency.

D. *Special provisions*—1. *Consent of both parents.* Even where State law may permit one parent alone to consent to medical care, both parents have an interest in the child, and therefore, consent of both parents should be obtained before any child may participate in research activities. Since the risks of research entail the possibility of additional burdens of care and support, the consent of both parents to the assumption of those risks should be obtained,[4] except when the identity or whereabouts of either cannot be ascertained or either has been judged mentally incompetent. If the consent of either parent is not obtained, written explanation or justification should be provided to the Protection Committee. Consent of school or institutional authorities is no substitute for parental concern and consent.

2. *The child's consent.* An important addition to the requirement for parental consent is the consent of the child subject. Clearly infants have neither the comprehension nor the independence of judgment essential to consent; older children might or might not have these capabilities. Although children might not have the capacity to consent on their own to participate in research activities, they must be given the opportunity (so far as they are able) to refuse to participate. The traditional requirement of parental consent for medical procedures is intended to be protective rather than coercive. Thus, while it was held to be unlawful to proceed merely with the consent of the child, but without consent of the parent or legal guardian,[5] the reverse should also hold. Therefore, in addition to consent of both parents, consent of the child subject must also be obtained when the child has attained the common law "age of discretion" of 7 years, unless the agency Ethical Review Board specifically exempts a project from this requirement.

3. *Exclusions.* Despite all the protections afforded by these procedures, certain children are categorically excluded from participation in research involving risk. These include children with no natural or adoptive parents available to participate in consent deliberations, and children detained by court order in a residential facility, whether or not natural or adoptive parents are available.

E. *The fetus.* Respect for the dignity of human life must not be compromised whatever the age, circumstance, or expectation of life of the individual. Therefore, all appropriate procedures providing protection for children as subjects in biomedical research must be applied with equal rigor and with additional safeguards to the fetus.

The recent decision of the Supreme Court on abortion[6] does not nullify the ethical obligation to protect the developing fetus from avoidable harm. This obligation, along with the right of every woman to change her decision regarding abortion, requires that no experimental procedures entailing risk to the fetus be undertaken in anticipation of abortion. Further, since the fetus might be at risk in research involving pregnant women, all research involving pregnant women must be reviewed by the Ethical Review Board, unless the Primary Review Committee determines that the research involves no risk to the fetus. Recruitment of pregnant subjects for research reviewed by the Board must involve the institution's Protection Committee in a manner approved by the Board, to provide supplementary judgment.

The consent of both parents must be obtained for any research involving the fetus, any statutes to the contrary on consent for abortion notwithstanding. Both the mother and the father have an interest in the fetus, and legal responsibility for it, if it is born. Therefore, the father's consent must be obtained for experimental procedures involving the fetus; consent of the father may be waived if his identity or whereabouts cannot be ascertained, or if he has been judged mentally incompetent.

IV. *Special categories*—A. *The abortus.* Prematurity is the major cause of infant death in this country; thus, research aimed at developing techniques to further viability is of utmost importance. Such research has already contributed significantly to improvement in the care of the pregnant woman and of her fetus. In addition, knowledge of fetal drug metabolism, enzyme activity, and the development of organs is essential to progress in preventing or offsetting certain congenital defects. After thorough research in animal models, it often eventually becomes essential to undertake studies in the non-viable human fetus.

The decision of the Supreme Court on abortion does not eliminate the ethical issues involved in research on the non-viable human fetus. No procedures should be undertaken on the non-viable fetus which clearly affront societal values. Nevertheless, certain research is essential to improve both the chance of survival and the health status of premature infants. Such research must meet ethical standards as well as show a clear relation either to the expectation of saving the life of premature infants through the development of rescue techniques, or to the furthering of our knowledge of human development and thereby our capacity to offset the disabilities associated with prematurity. It is imperative, however, that the investigator first demonstrate that appropriate studies on animals have in fact been exhausted and that therefore the research in question requires that the work be done on the non-viable human fetus. Specific reasons for this necessity must be identified. A thorough review of the ethical issues in proposed research involving the non-viable fetus is of utmost importance.

It must be recognized that consent for abortion does not necessarily entail disinterest on the part of the pregnant woman in what happens to the product of conception. Some women feel strongly about what may, or may not, be done to the aborted fetus; others do not. In order to give every woman the opportunity to declare her wishes, consent of the pregnant woman for application of any research procedures to the aborted fetus must be secured at the time of admission to the hospital for the abortion.

Because research on the abortus involves ethical as well as scientific issues, all projects involving the abortus must be reviewed by the Ethical Review Board, and recruitment of individual pregnant women for such research must involve the institution's Protection Committee in a manner approved by the Board to provide supplementary judgment. In addition to the requirement for maternal consent, both the Ethical Review Board and the Protection Committee shall, in their deliberations, consider the ethical and social issues surrounding research on the non-viable fetus. The Protection Committee must be satisfied that maternal consent is freely given and based on full disclosure, each time approved research is conducted on an abortus.

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[4] 59 *Am. Jur.* 2d, Sect. 129, p. 229.

[5] *Bonner v. Moran*, 75 U.S. App. D.C. 156, 126 F. 2d 121, 139 A.L.R. 1366 (1941).

[6] *Roe v. Wade*, 410 U.S. 113 (1973).

In order to insure that research considerations do not influence decisions as to timing, method, or extent of a procedure to terminate a pregnancy, no investigator engaged in the research on the abortus may take part in these decisions. These are decisions to be made by the woman and her physician.

The attending physician, not the investigator, must determine the viability of the abortus at the termination of pregnancy. If there is a reasonable possibility that the life of the fetus might be saved, experimental and established methods may be used to achieve that goal. Artificial life-support techniques may be employed only if the physician of record determines that the fetus might be viable. If the physician determines that the fetus is not viable, it is not acceptable to maintain heart beat or respiration artificially in the abortus for the purpose of research. Experimental procedures which of themselves will terminate respiration and heart beat may not be undertaken.

This policy and these protections apply with equal force to the products of spontaneous abortions.

B. *The products of in vitro fertilization.* In the interest of improving human health and development, the biology of human fertilization and the early events surrounding this phenomenon, including implantation, should be studied. To the extent that in vitro studies of human fertilization might further this aim, they are permissible at the present time within the limits outlined below.

Current technology limits the in vitro development of the human fertilized ovum to a period of several days. This is a rapidly advancing field of biomedical research, however, and the time might come when it is possible to extend in vitro development beyond the stage of early cell division and possibly even to viability.

It is contrary to the interests of society to set permanent restrictions on research which are based on the successes and limitations of current technology. Still, it is necessary to impose restraints prospectively in order to provide reasonable protections, while at the same time permitting scientific advancements which might well benefit society. A mechanism is required to weigh, at any given time, the state of the art, a specific proposal, legal issues, community standards, and the availability of guidelines to govern the research situation. This mechanism is provided by the Ethical Review Board. Ultimately, the Board will determine the acceptability of a project involving in vitro fertilization, and by recognizing the state of the art, as well as societal concerns, propose appropriate research policy.

Care must be taken not to bring human ova fertilized *in vitro* to viability—whether in the laboratory or implanted in the uterus—until the safety of the technique has been demonstrated as far as possible in sub-human primates. To this end:

1. All proposals for research involving human in vitro fertilization must be reviewed by the Ethical Review Board.

2. No research involving the implantation of human ova fertilized in the laboratory into recipient women should be supported until the appropriate scientific review boards are satisfied that there has been sufficient work in animals (including sub-human primates) to demonstrate the safety of the technique. It is recommended that this determination of safety include studies of natural born offspring of the products of in vitro fertilization.

3. No implantation of human ova fertilized in the laboratory should be attempted until guidelines are developed governing the responsibilities of the donor and recipient "parents" and of research institutions and personnel.

V. *Prisoners—A. Policy considerations.* Clinical research often requires the participation of normal volunteers; for example, in the early stages of drug or vaccine evaluation. Sometimes, the need for standardization certain variables, or for monitoring responses over an extended period of time, requires that the subjects of research remain in a controlled environment for the duration of the project. Prisoners may be especially suitable subjects for such studies, since, unlike most adults, they can donate their time to research at virtually no cost to themselves. However, the special status of prisoners requires that they have special protection when they participate in research.

While there is no legal or moral objection to the participation of normal volunteers in research, there are problems surrounding the participation of volunteers who are confined in an institution. Many aspects of institutional life may influence a decision to participate; the extent of that influence might amount to coercion, whether it is intended or not. Where there are no opportunities for productive activity, research projects might offer relief from boredom. Where there are no opportunities for earning money, research projects offer a source of income. Where living conditions are unsatisfactory, research projects might offer a respite in the form of good food, comfortable bedding, and medical attention. While this is not necessarily wrong, the inducement (compared to the deprivation) might cause prisoners to offer to participate in research which would expose them to risks of pain or incapacity which, under normal circumstances, they would refuse. In addition, there is always the possibility that the prisoner will expect participation in research to be viewed favorably, and to his advantage, by prison authorities (on whom his other few privileges depend) and by the parole board (on whom his eventual release depends). This is especially true when the research involves behavior modification and may be termed "therapeutic" with respect to the prisoner. In such instances, participation inevitably carries with it the hope that a successful result will increase the subject's chances for parole. Thus, the inducement involved in therapeutic research might be extremely difficult to resist; and for this reason, special protection is necessary for prisoners participating in research, whether or not the research is therapeutic.

The first principle of the Nuremburg Code requires that subjects of biomedical research must be "so situated as to be able to exercise free power of choice" concerning their participation. Whether prisoners can be considered to be "so situated" is ultimately a matter for the courts and the legislatures to resolve. In the meantime, it must be recognized that where liberty is limited, and where freedom of choice is restricted, there is a corresponding limitation of the capacity to give truly voluntary consent. Although the prisoner might be adequately informed, and competent to make judgments, the voluntariness of the person's consent remains open to question. This policy statement is designed to provide additional protections to prisoners participating in research.

The mission of the Department of Health, Education, and Welfare does not include rendering judgments on the administration of justice or the management of the correctional system. At the same time, the Department should not support activities which take unethical advantage of those who are under the jurisdiction of the courts and who, for that reason, lack some of the usual defenses to their personal integrity. Participation of prisoners in the research activities of the DHEW in the pursuit of medical knowledge might be beneficial to all concerned, but the relationship which involves a class of persons with diminished autonomy requires careful supervision.

Many prisoners are strongly motivated to participate in research, and view as unfair suggestions that they be denied this opportunity. Unless society, through its judicial and legislative bodies, decides that such participation should be halted, it is essential to develop mechanisms to protect those who may participate, or who are now participating, from the coercive aspects of incarceration which diminish their capacity for voluntary consent. Pursuant to the obligation to protect the rights of all subjects participating in research conducted under its auspices, the DHEW is proposing special guidelines for the protection of prisoners as subjects in any biomedical or behavioral research.

Two aspects of research involving prison populations require special review and procedural safeguards in addition to those provided by current DHEW policies.

First, when research is conducted under the auspices of a commercial manufacturer or an individual investigator, it is not always subject to review by an Organizational Review Committee, as is required for similar research conducted at a hospital or a university. Thus, local review has not heretofore been required for ethical considerations or for specific problems related to the population or institution which is to be directly involved. Second, because of the loss of individual dignity, the limitations of personal freedom, and the possibility of real or potential coercion which may accompany confinement in an institution, special safeguards must be provided to mitigate the inequalities of bargaining power between the prisoners and those who are in positions of authority. While it is important that prisoners have the opportunity to participate in research, it is equally important that they not feel compelled to do so.

B. *Organizational Review Committee.* All research involving prisoners must be conducted at an accredited correctional facility (see Section F, below) and be reviewed initially, and on a continuing basis, either by the Organizational Review Committee of that correctional facility or by the Organizational Review Committee of the institution sponsoring the research. The Organizational Review Committee shall have the duties and responsibilities identified in current DHEW regulations. In addition, for each project, it shall determine the adequacy of clinic or hospital facilities for the particular activity to be conducted, assess the appropriateness of the subject population for that activity, and weigh the questions of scientific importance, social need, and ethical acceptability. In addition to the foregoing, the Organizational Review Committee shall have the following duties, with respect to research involving prisoners as subjects:

1. To review and approve or modify the process proposed by the principal investigator for involvement of the Protection Committee (see below) in overseeing the selection of subjects who may be included in the research, and the process of obtaining their voluntary and informed consent.

2. To set rates of remuneration, if any, consistent with the expected duration and discomfort or risk of the proposed study, and consistent with other opportunities for employment, if any, at the facility in question.

3. To monitor the progress of the research as required by the sponsoring DHEW agency.

The recommendations of this Committee, along with a report describing any site visits, shall be included with the investigator's application to the agency. For facilities which have filed no general assurance, composition as well as recommendations of the Organizational Review Committee will be considered an integral part of the proposal in the agency review.

C. *Protection Committee.* The primary function of the Protection Committee is to provide supplementary judgment by overseeing the selection of subjects who may be included in a research project to assure that their consent is as voluntary as possible under the conditions of confinement.

Consent is a continuing process. To assure the voluntariness of consent, subjects must be able to withdraw from the research project without prejudice. Each Protection Committee shall establish such a withdrawal mechanism.

The duties of the Protection Committee, therefore, shall include:

1. Reviewing the information given the potential subjects, with special attention to: adverse effects, the importance of reporting all deviations from normal function, the continuing option of withdrawing from participation at any time, and the identification of a member of the committee who will be available, at reasonable intervals upon request, for consultation regarding the research project. All of this information shall appear on the consent form, a copy of which will be given to each participant. When oral representations are made procedures described under DHEW regulations shall be followed.

2. Overseeing the process of selection of subjects who may be included in the research, to the extent stipulated in the recommendation of the Organizational Review Committee. This may vary from overall approval of the recruitment process, to reviewing a sample of subject selections, to interviewing as a full Committee each individual subject to be included in the project.

3. Visiting the institution on a regular basis to invite questions, to monitor the progress of the research, and to assess the continued willingness of subject participation. The frequency of these visits will be determined by the nature of the research, and any recommendations of the Organizational Review Committee. Depending upon the circumstances and the number of subjects involved, these visits may be made either on a rotating basis by various members of the Committee, or by the full Committee.

4. Maintaining records of its activities including contacts initiated by subjects in the project between regular site visits. These records shall be made available to the agency upon request.

The Protection Committee shall be comprised of at least 5 members so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved. No more than ⅓ of the members shall be scientists engaged in biomedical research or physicians; at least 1 shall be a prisoner or a representative of an organization concerned with the prisoners' interests; no more than 1 (except prisoners or their representatives) shall have any affiliation with the prison facility or with the unit of government having jurisdiction over the facility, with the exception of persons employed by the department of education of a relevant jurisdiction in a teaching capacity. The composition and the investigator's proposed use of the Committee must be reviewed and approved by the DHEW agency.

D. *Payment to prisoners.* The amount paid for participation in research will vary according to the risks and discomforts involved, and the other employment opportunities in the facility in which the research is to be conducted. The specific amount for each project will be determined by the Organizational Review Committee, which will forward its recommendation as part of the application to the sponsoring agency. The amount paid shall provide a compensation for services, but shall not be so great as to constitute undue inducement to participate.

Any reduction of sentence as a consequence of participation in research shall be comparable to other opportunities at the facility for earning such a reduction.

Any subject who is required by the investigator or prison physician to withdraw, for medical reasons, before completion of the investigation, shall continue to be paid for a period to be determined by the Protection Committee in consultation with the investigator. This does not apply to subjects who withdraw for other reasons. Any disputes regarding certification of withdrawal for medical reasons shall be heard and resolved by the Protection Committee.

Prisoners who serve on the Protection Committee shall be paid an amount consistent with that received by the research subjects.

E. *Accreditation.* The Secretary, DHEW, shall establish standards for accreditation of correctional facilities offering to act as sites for the performance of clinical research, or offering to act as a source of volunteer subjects for clinical research when the research is supported in whole or in part by Departmental funds or the research is to be performed in compliance with requirements of Federal statutes.

The review for certification shall include, but not be limited to:

1. Standard of living in the prison facility.

2. Other opportunities for employment and/or constructive activity, either within the prison, or in a work-release program.

3. Adequacy of (a) medical care for the general prison population (so that participation in research is not the only means of obtaining medical attention), and (b) the proposed methods for maintaining medical records and for protecting the confidentiality of those records.

4. The nature, structure, function, and composition of the Organizational Review Committee (whether located at the prison or at the institution sponsoring the research) which is to review clinical research in that correctional facility.

The Secretary shall also set general guidelines to assist the Organizational Review Committees in determining rates of remuneration, and shall indicate groups who may be considered to represent the prisoners' interests for the purpose of appointment to membership on the Protection Committee. No institution shall be accredited if research, whether or not supported by funds from the DHEW, is conducted under its auspices, or by members of its staff, which is not in conformity with these guidelines. No DHEW funds will be granted for research in institutions lacking such accreditation.

F. *Special provisions*. 1. Persons detained in a correctional facility while awaiting sentence, or in a hospital facility for pre-sentence diagnostic observation, are excluded from participation in research.

2. A child may not be included as a subject in research involving risk if he is detained in an institutional setting pursuant to a court order, whether or not the parents and the child have consented to the child's participation.

VI. *The mentally infirm*.—A. *Policy considerations*. The institutionalized mentally infirm are doubly limited with respect to participation in research activities. First, as with children, they might lack the clear capacity to comprehend relevant information, and to make informed judgments concerning their participation. Second, as with prisoners, they experience a diminished sense of personal integrity as a result of confinement in an institution. Such confinement restricts their freedom of choice and imposes elements of coercion, which limit their capacity to give truly voluntary consent. In addition, the mentally infirm who are confined in institutions have more pressures to cooperate with custodial authorities than do prisoners, for their release might depend entirely upon their behavior and on the impression they make upon those having the power to make decisions concerning termination of their confinement.

Legal guardians, who have authority to consent for medical treatment, might have interests in the matter which do not necessarily coincide with those of the patient. Long-term management of patients with mental disabilities is expensive and time-consuming. Any proposal which might reduce either the expense or the supervision required in caring for such persons might be appealing, whether or not there is correlative benefit to the patient. This is certainly the case in projects offering new therapy; it might also occur, albeit in a more subtle form, where free medical or custodial services are perceived to be contingent upon the patient's participation as a subject in research.

The courts have begun to recognize that persons confined in institutions might not be able to give truly voluntary consent in such matters. It is important to recognize, as well, that persons encumbered with the economic or custodial responsibility for the mentally infirm might not be sufficiently objective to make judgments which are fully in the best interest of the institutionalized person.

The circumstances are limited under which it is justifiable to include the mentally infirm as subjects in biomedical research. These circumstances include projects in which: the proposed research concerns diagnosis, treatment, prevention, or etiology of the disability from which they suffer; the necessary information can be obtained only from those subjects; or the studies concern institutional life *per se*. With these exceptions, the general rule is that the participation of the mentally infirm as subjects in research is not acceptable.

B. *Ethical review of projects and protection of subjects*. In instances in which a research protocol requires the participation of mentally infirm subjects, the research must be overseen by a Protection Committee in the manner described in Section III–C, pertaining to children. This Protection Committee must be supervised on a continuing basis, as described in Section V–B, by the Organizational Review Committee of the institution in which the research is to be conducted or of the institution sponsoring the research.

VII. *General provisions*. These provisions apply to all research activities covered by this policy.

A. *Referrals to the Ethical Review Board*. Whenever a Primary Review Committee, secondary review group, or the agency staff perceives an apparent and significant question of ethics or an unusual element of risk—whatever the subject group involved—the research proposal in question may be forwarded to the Ethical Review Board for an opinion. In addition to offering an opinion of acceptability from an ethical viewpoint, the Board may choose to recommend the establishment of a Protection Committee, and suggest guidelines for its operation.

B. *Procedures requiring special consideration*. All other recommendations notwithstanding, DHEW may identify certain procedures which: (1) Require Protection Committee review of the selection of each individual subject; (2) are acceptable for stipulated subjects only if approved by affirmative declaratory judgment of a court of competent jurisdiction; or (3) are unacceptable.

C. *Research conducted in Foreign Countries*. All regulations governing research conducted in the United States apply to research conducted in foreign countries under DHEW auspices, and the ethical review must be of equal rigor.

There are sometimes special constraints encountered in foreign settings. Therefore, in addition to the requirement that consent procedures for research to be conducted abroad conform with the policy and regulations set forth in this document, there must be written assurance that the proposed research enjoys local acceptance, and offends no local ethical standards.

D. *Research submitted pursuant to DHEW regulatory requirements*. Research or testing which is performed pursuant to or in fulfillment of any regulation issued by any agency of the DHEW will be acceptable to the government only if conducted in compliance with these procedures and regulations.

E. *Clinical research not funded by DHEW*.

If, in the judgment of the Secretary, an organization has failed to comply with the terms of this policy with respect to a particular DHEW grant or contract, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

If, in the judgment of the Secretary, an organization fails to discharge its responsibilities for the protection of the rights and welfare of the subjects in its care, whether or not DHEW funds are involved, he may, upon reasonable notice to the organization of the basis for such action, determine that its eligibility to receive further DHEW grants or contracts involving human subjects shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

If, in the judgment of the Secretary, an individual serving as principal investigator, program director, or other person having responsibility for the scientific and technical direction of a project or activity, has failed to discharge his responsibilities for the protection of the rights and welfare of human subjects in his care, the Secretary may, upon reasonable notice to the individual of the basis for such action, determine that such individual's eligibility to serve as a principal investigator or program director or in another similar capacity shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.[7]

In reaching a determination on compliance, with respect to subjects with limited capacity for consent, the Secretary will consider the extent and the nature of the procedures by which the institution offers protection in all studies conducted in or by that institution regardless of the source of funds, with the expectation that there shall be an ethical review similar to that required of the agency Ethical Review Board (III–B). The existence of a Protection Committee, overseen by an Organizational Review Committee and acting to afford supplementary judgment, will be accepted as evidence of responsibility in this regard.

F. *Confidentiality of information and records*. Nothing in this policy shall be construed as permitting the release of confidential research protocols nor the violation of State law applicable to the confidentiality of individual medical records.

VIII. *Draft additions to proposed regulations* (See FEDERAL REGISTER, Vol. 38, No. 194, Part 2, Tues., Oct. 9, 1973, pp. 27882–27885).

To amend the proposed Part 46 of Subtitle A of Title 45 of the Code of Federal Regulations by deleting §§ 46.20 through 46.23, redesignating §§ 46.1 through 46.19 thereof as Subpart A, and adding the following new Subparts B through F:

SUBPART B—ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Sec.
46.21 Applicability.
46.22 Purpose.
46.23 Need for legally effective consent.
46.24 Definitions.
46.25 Ethical Review Board; Composition; Duties.

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[7] FEDERAL REGISTER, Vol. 38, No. 194, Part 2, Tuesday, October 9, 1973, § 46.22, p. 27885.

Sec.
46.26 Protection Committees; Composition; Duties.
46.27 Certain children excluded from participation in DHEW supported activities.
46.28 Activities to be performed outside the United States.

SUBPART C—ADDITIONAL PROTECTIONS FOR CERTAIN CLASSES OF DHEW ACTIVITIES

46.31 Applicability.
46.32 Purpose.
46.33 Definitions.
46.34 Duties of the Ethical Review Board.
46.35 Maternal consent to activities involving the abortus.
46.36 Additional conditions for activities involving the abortus.
46.37 Prohibition on certain activities involving pregnant women where the fetus may be adversely affected.
46.38 Parental consent to activities which may affect the fetus.
46.39 Activities to be performed outside the United States.

SUBPART D—ADDITIONAL PROTECTIONS FOR PRISONERS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Sec.
46.41 Applicability.
46.42 Purpose.
46.43 Definitions.
46.44 Additional duties of Organizational Review Committee where prisoners are involved.
46.45 Protection Committees; Duties; Composition.
46.46 Prohibition on participation in activities prior to conviction.
46.47 Remuneration to subjects.
46.48 Accreditation.
46.49 Activities to be performed outside the United States.

SUBPART E—ADDITIONAL PROTECTIONS FOR THE INSTITUTIONALIZED MENTALLY INFIRM INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

46.51 Applicability.
46.52 Purpose.
46.53 Definitions.
46.54 Limitations on activities involving the institutionalised mentally infirm.
46.55 Additional duties of Organizational Review Committee where the mentally infirm are involved.
46.56 Protection Committees; Duties; Composition.
46.57 Activities to be performed outside the United States.

SUBPART F—GENERAL PROVISIONS

46.61 Applicability.
46.62 Organization's records.
46.63 Reports.
46.64 Early termination of awards; sanctions for noncompliance.
46.65 Conditions.

AUTHORITY: 5 U.S.C. 301.

SUBPART B—ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED AS SUBJECT IN DHEW ACTIVITIES

Section 46.21 *Applicability*. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, or demonstration activities in which children may be at risk.

(b) The requirements of this subpart are in addition to those imposed under subpart A of this part.

Section 46.22 *Purpose*. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable inasmuch as the potential subjects in activities conducted thereunder might be unable fully to comprehend the risks which might be involved and are legally incapable of consenting to their participation in such activities.

Section 46.23 *Need for legally effective consent*. Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in any activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

Section 46.24 *Definitions*. As used in this subpart:

(a) '"DHEW activity" means:

(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(b) "Subject at risk" means any individual who might be exposed to the possibility of harm—physical, psychological, sociological, or other—as a consequence of participation as a subject in any DHEW activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

(c) "Child" means an individual who has not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which such research is to be conducted.

(d) "DHEW" means the Department of Health, Education and Welfare.

Section 46.25 *Agency Ethical Review Board; composition; duties*. (a) The head of each agency shall establish an Ethical Review Board, hereinafter referred to as the "Board," to review proposals for research, development, and demonstration activities to which this subpart is applicable, as well as to advise him or her on matters of policy concerning protection of human subjects. The Board shall be composed of research scientists (biomedical, behavioral, and/or social), physicians, lawyers, clergy, ethicists, and representatives of the public. It shall consist of 15 members appointed by the agency head from outside the Federal Government. No more than one-third of the members may be individuals engaged in research, development, or demonstration activities involving human subjects.

(b) It shall be the function of the Board to review each proposed activity to which this subpart applies, and advise the agency concerning the acceptability of such activities from the standpoint of societal need and ethical considerations, taking into account the assessment of the appropriate Primary Review Committees as to: (1) The potential benefit of the proposed activity, (2) scientific merit and experimental design, (3) whether the proposed activity entails risk of significant harm to the subject, (4) the sufficiency of animal and adult human studies demonstrating safety and clear potential benefit of the proposed procedures and providing sufficient information on which to base an assessment of the risks, and (5) whether the information to be gained may be obtained from further animal and adult human studies.

(c) The Board shall review the procedures proposed by the applicant to be followed by the Protection Committee, provided for in § 46.26 of this subpart, in carrying out its functions as set forth in § 46.26. In addition, the Board may recommend additional functions to be performed by the Protection Committee in connection with any particular activity.

(d) In decisions regarding activities covered by this subpart, the agency shall take into account the recommendations of the Board.

Section 46.26 *Protection Committees; composition; duties*. (a) No activity covered by this subpart will be approved unless it provides for the establishment by the applicant of a Protection Committee, composed of at least five members so selected that the Committee will be competent to deal with the medical, legal, social and ethical issues involved in the activity. None of the members shall have any association with the proposed activity, and at least one-half shall have no association with any organization or individual conducting or supporting the activity. No more than one-third of the members shall be individuals engaged in research, development, or demonstration activities involving human subjects. The composition of the Protection Committee shall be subject to DHEW approval.

(b) The duties of the Protection Committee, proposed by the applicant, and reviewed by the agency including the Ethical Review Board shall be to oversee: (1) The selection of subjects who may be included in the activity; (2) the monitoring of the subject's continued willingness to participate in the activity; (3) the design of procedures to permit intervention on behalf of one or more of the subjects if conditions warrant; (4) the evaluation of the reasonableness of the parents' consent and (where applicable) the subject's consent; and (5) the procedures for advising the subject and/or the parents concerning the subject's continued participation in the activity. Each subject and his or her parent or guardian will be informed of the name of a member of the Protection Committee who will be available for consultation concerning the activity.

(c) The Protection Committee shall establish rules of procedure for conducting its activities, which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained.

Section 46.27 *Certain children excluded from participation in DHEW activities*. A child may not be included as a subject in DHEW activities to which this subpart is applicable if:

(a) The child has no known living parent who is available and capable of participating in the consent process: *Provided*, That this exclusion shall be inapplicable if the child is seriously ill, and the proposed research is designed to substantially alleviate his condition; or

(b) The child has only one known living parent who is available and capable of participating in the consent process, or only one such parent, and that parent has not given consent to the child's participation in the activity; or

(c) Both the child's parents are available and capable of participating in the consent process, but both have not given such consent;

(d) The child is involuntarily confined in an institutional setting pursuant to a court order, whether or not the parents and child have consented to the child's participation in the activity; or

(e) The child has not given consent to his or her participation in the research: *Provided*, That this exclusion shall be inapplicable if the child is 6 years of age or less or if explicitly waived by the DHEW; or

(f) The Protection Committee established under § 46.26 of this subpart has not reviewed and approved the child's participation in the activity.

Section 46.28 *Activities to be performed outside the United States*. In addition to satisfying all other applicable requirements in this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART C—ADDITIONAL PROTECTION FOR CERTAIN CLASSES OF DHEW ACTIVITIES

Section 46.31 *Applicability*. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, or demonstration activities: (1) Involving pregnant women, unless there is a finding by DHEW that the activity will have no adverse effect on the fetus, or is clearly thereapeutic with respect to the fetus involved, (2) involving the abortus or the non-viable fetus, or (3) involving in vitro fertilization of human ova.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) To the extent the requirements of subpart A of this part are applicable to activities also covered by this subpart, the requirements of this subpart are in addition to those imposed under subpart A.

Section 46.32 *Purpose*. It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

Section 46.33 *Definitions*. As used in this subpart:

(a) "DHEW" means the Department of Health, Education, and Welfare.

(b) "DHEW activity" means:

(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(c) "Board" means the Board established under § 46.25.

(d) "Protection Committee" means a committee referred to in § 46.26.

(e) "Pregnancy" means the period of time from implantation of a fertilized ovum until delivery.

(f) "Fetus" means the product of conception from implantation until delivery.

(g) "Abortus" means the fetus when it has been expelled whole, whether spontaneously or as a result of medical or surgical intervention to terminate a pregnancy, prior to viability. This definition, for the purpose of this policy, excludes the placenta, fetal material which is macerated at the time of expulsion, a dead fetus, and isolated fetal tissue or organs excised from a dead fetus.

(h) "Viability of a fetus" means capability given the benefit of available therapy, of independently maintaining heart beat and respiration.

(i) "In vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, through admixture of human sperm and such ova.

Section 46.34 *Duties of the Ethical Review Board*. (a) It shall be the function of the Board to review each activity to which this subpart applies and advise the agency concerning the acceptability of such activities from the standpoint of societal need and ethical considerations, taking into account the assessment of the appropriate Primary Review Committees as to: (1) The potential benefit of the proposed activity, (2) scientific merit and experimental design, (3) the sufficiency of studies involving animals demonstrating the clear potential benefit of the proposed procedures and (4) whether the information to be gained may be obtained from further animal or adult human studies.

(b) The Board may recommend the establishment by the sponsoring institution of a Protection Committee to carry out such functions as the Board deems necessary.

Section 46.36 *Maternal consent to activities involving the abortus*. (a) No activity to which this subpart is applicable may involve an abortus or a non-viable fetus unless maternal consent has been obtained.

(b) No activity to which this subpart is applicable may involve an abortus or a non-viable fetus unless: (1) Individuals involved in the activity will have no part in the decision as to timing, method, or extent of the procedure used to terminate the pregnancy, or in determining viability of the fetus at the termination of the pregnancy; (2) vital functions of the abortus will not be maintained artificially for purposes of research; and (3) experimental procedures which would terminate heart beat or respiration in the abortus will not be employed.

Section 46.37 *Prohibition on certain activities involving pregnant women where the fetus may be adversely affected*. The Board shall review all research, development, and demonstration activities involving pregnant women. No activity to which this subpart is applicable may involve a pregnant woman if the Primary Review Committee finds that the fetus might be adversely affected, unless the primary purpose of the activity is to benefit that fetus. In addition, no activity to which this subpart is applicable may involve pregnant women unless all the requirements of this subpart are satisfied.

Section 46.38 *Parental consent to activities which might affect the fetus*. No activity involving a pregnant woman which might affect the fetus but which nevertheless is permissible under § 46.37 shall be conducted unless maternal consent has been obtained, as well as the consent of the father if he is available and capable of participating in the consent process.

Section 46.39 *Activities to be performed outside the United States*. In addition to satisfying all other applicable requirements in this subpart, activities to which this subpart is applicable, which are to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART D—ADDITIONAL PROTECTIONS FOR PRISONERS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Section 46.41 *Applicability*. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare research, development, and demonstration activities involving prisoners as subjects.

(b) The requirements of this subpart are in addition to those imposed under subparts A and B of this part.

Section 46.42 *Purpose*. It is the purpose of this subpart to provide additional safeguards for activities to which this subpart is applicable inasmuch as the potential subjects in activities conducted thereunder, because of their incarceration, might be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate in such activities.

Section 46.43 *Definitions*. As used in this subpart:

(a) "DHEW activity" means:

(1) the conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) research, development, or demonstration activities regulated by any DHEW agency.

(b) "Prisoner" means any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute and also individuals detained by virtue of statutes which provide alternatives to criminal prosecution.

(c) "DHEW" means the Department of Health, Education, and Welfare.

Section 46.44 *Additional duties of Organizational Review Committees where prisoners are involved*. (a) In carrying out its responsibilities under subpart A of this part for activities also covered by this subpart, the Organizational Review Committee provided for under subpart A shall also certify: (1) That there will be no undue inducements to participation by prisoners as subjects in the activity, taking into account among other factors, the sources of earnings generally available to the prisoners as compared with those offered to participants in the activity, (2) that the clinic and hospital facilities are adequate for the proposed activity, (3) that all aspects of the activity would be appropriate for performance on nonprisoners, and (4) that no prisoner will be offered any reduction in sentence or parole for participation in such activity which is not comparable to that offered for other activities at the facility not of a research, development, demonstration or similar nature.

(b) In addition, the Organizational Review Committee shall have the following duties: (1) To review, approve, or modify the procedures proposed for the Protection Committee in carrying out its functions as set forth in § 46.45; (2) To recommend any additional functions to be performed by the Protection Committee in connection with a particular activity; (3) To set rates of remuneration, if any, consistent with the anticipated duration, discomfort, and/or risk of the activity but not in excess of that paid for other employment generally available to inmates of the facility in question; and (4) To carry out such other responsibilities as may be stipulated by DHEW in the contract or grant award.

(c) Activities to which this subpart is applicable must provide for the designation of an Organizational Review Committee, where no such Committee has been established under subpart A.

Section 46.45 *Protection Committees; duties; composition*. (a) No activity covered by this subpart will be approved unless it provides for the establishment of a Protection Committee to carry out the following functions, as well as any others recommended by the Organizational Review Committee or by DHEW: (1) Reviewing the procedure for soliciting participation by prisoners in the research activity to determine that all elements of informed consent, as outlined in § 46.3, are satisfied; (2) overseeing the selection of prisoners who may participate in the activity; (3) monitoring the progress of the research and the continued willingness of subject participation; and (4) intervening on behalf of one or more subjects if conditions warrant. In addition, each subject will be informed of the name of a member of the Protection Committee who will be available to the subject for consultation concerning the activity.

(b) Each Protection Committee shall be composed of at least five members appointed by the applicant and so selected that the Committee will be competent to deal with the medical, legal, social, and ethical issues involved. At least one member of the Committee shall be either a prisoner or a representative of an organization having as a primary concern protection of the interests of prisoners.

No more than one-third of the members may be physicians or scientists engaged in biomedical or behavioral research, and no more than one member, other than a prisoners' representative, may have any affiliation with the prison facility or the legal entity having jurisdiction over the facility, except for persons employed by a Department of Education in a teaching capacity. Any prisoners serving on the Committee shall be compensated at a rate consistent with that set for prisoners participating as subjects in activities at the facility to which this subpart is applicable.

(c) The Protection Committee shall establish rules of procedure for conducting its activities which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained. The composition of the Committee shall be subject to DHEW approval.

Section 46.46 *Prohibition on participation in activities prior to conviction*. No individual confined pending arraignment, trial, or sentencing for an offense punishable as a crime may be used as a subject in any activity supported in whole or in part by a grant or contract to which this subpart is applicable.

Section 46.47 *Remuneration to subjects*. Where rates of remuneration are set pursuant to § 46.44 of this subpart, any subject who, for medical reasons, is required by a representative of the prison facility, grantee, contractor, or sponsor of the activity, to withdraw before completion of his or her participation in the activity shall continue to be compensated for a period to be set by the Protection Committee after consultation with the grantee or contractor.

Section 46.48 *Accreditation*. It is the intention of DHEW to accredit prison facilities as sites for the performance of activities to which this subpart applies. Accreditation will be based on certification of the acceptability of the facilities and compliance with the procedures required by this subpart, as determined by the Secretary. No activity covered by this subpart may involve prisoners incarcerated in a facility not accredited by Secretary of DHEW.

Section 46.49 *Activities to be performed outside the United States*. In addition to satisfying all other applicable requirements in this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART E—ADDITIONAL PROTECTIONS FOR INSTITUTIONALIZED MENTALLY INFIRM INDIVIDUALS INVOLVED AS SUBJECTS IN DHEW ACTIVITIES

Section 46.51 *Applicability*. (a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare activities involving the institutionalized mentally infirm as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein in connection with activities permitted under § 46.54 of this subpart will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity; nor in particular does it obviate the need for court approval of such participation where court approval is required under applicable State or local law in order to obtain a legally effective consent.

(c) The requirements of this subpart are in addition to those imposed under Subparts A, B, and D of this part.

Section 46.52 *Purpose*. It is the purpose of this subpart to provide additional safeguards for the mentally infirm involved in research, development, and demonstration activities, inasmuch as the potential subjects in such activities are: (1) Confined in an institutional setting; (2) might be unable fully to comprehend the type risks which may be involved; and (3) might be legally incompetent to consent to their participation in such activities.

Section 46.53 *Definitions*. As used in this subpart:

(a) "DHEW activity" means:

(1) The conduct or support (through grants, contracts, or other awards) of biomedical or behavioral research involving human subjects; or

(2) Research, development, or demonstration activities regulated by any DHEW agency.

(b) "Mentally infirm" includes the mentally ill, the mentally retarded, the emotionally disturbed, the psychotic, the senile, and others with impairments of a similar nature, regardless of whether or not the individual has been determined to be legally incompetent.

(c) "Institutionalized" means confined, whether by court order or voluntary commitment, in an institution for the care and/or treatment of the mentally infirm.

Section 46.54 *Limitations on activities involving the institutionalized mentally infirm*. No institutionalized mentally infirm individual may be included as a subject in a DHEW activity unless:

(a) The proposed activity is concerned with: (1) The diagnosis, treatment, prevention, or etiology of the impairment with which he or she is afflicted; or (2) the proposed activity is concerned with the effect of institutional life on the subject and involves no risk of harm to the subject; or (3) the information can be obtained only from such subjects.

(b) The individual's legal guardian has given consent to the individual's participation in such activity;

(c) Where the individual has sufficient mental competency to understand what is proposed and to express an opinion as to his or her participation, the individual's consent to such participation has also been secured; and

(d) The Protection Committee, provided for in § 46.56 of this subpart, has reviewed and approved subject participation in the activity (by class or by individual).

Section 46.55 *Additional duties of Organizational Review Committee where the mentally infirm are involved*. (a) In addition to its responsibilities under Subpart A of this part, the Orgahizational Review Committiee shall, with respect to activities to which subpart applies:

(1) Certify that all aspects of the activity would be ethically appropriate for performance on healthy individuals;

(2) Conduct at least one on-site visit to the institution and prepare a report of the visit, including discussion of such matters as living conditions, availability of medical care, and quality of food, to be submitted to DHEW along with the application;

(3) Review and approve or modify the procedures proposed by the applicant to be followed by the Protection Committee, provided for in § 46.56, in overseeing the recruitment of the mentally infirm subjects who may be included in such activity;

(4) Recommend any additional functions to be performed by the Protection Committee in connection with any particular activity; and

(5) Carry out such other responsibilities as may be recommended by DHEW.

(b) Activities to which this subpart is applicable must provide for the designation of an Organizational Review Committee where no such Committee has been established under subpart A.

Section 46.56 *Protection Committees; duties; composition*. (a) No activity covered by this subpart will be approved unless it provides for the establishment of a Protection Committee to carry out the following functions, as well as any others prescribed by the Organizational Review Committee or by DHEW: (1) Overseeing the process of selection of subjects who may be included in the activity, (2) monitoring the progress of the activity with special attention to adverse effects on subjects, (3) intervening on behalf of one or more of the subjects if conditions warrant, (4) evaluating the process and reasonableness of consent of the legal guardian and (where applicable) of the subject, and (5) advising the legal guardian and/or the subject concerning the latter's continued participation in the activity if conditions warrant.

(b) The composition of each Protection Committee shall conform to the requirements set forth in § 46.26(a).

(c) The Protection Committee shall establish rules of procedure for conducting its activities, which must be reviewed by DHEW, and shall conduct its activities at convened meetings, minutes of which shall be prepared and retained.

Section 46.57 *Activities to be performed outside the United States*. In addition to satisfying all other applicable requirements in this subpart, an activity to which this subpart is applicable, which is to be conducted outside the United States, must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed.

SUBPART F—GENERAL PROVISIONS

Section 46.61 *Applicability*. The following regulations are applicable to all activities covered by this part.

Section 46.62 *Records*. (a) Copies of all documents presented or required for initial and continuing review by any Organizational Review Committee or Protection Committee and minutes, transmittals on actions, instructions, and conditions resulting from committee deliberations are to be made part of the official files of the grantee or contractor for the supported activity.

(b) Records of subject's and representative's consent shall be retained by the grantee or contractor in accordance with its established practice, or, if no practice has been established, in project files.

(c) Acceptance of any DHEW grant or contract award shall constitute consent of the grantee or contracting organization to inspection and audit of records pertaining to the assisted activity by authorized representatives of the Secretary.

(d) All documents and other records required under this part must be retained by the grantee or contracting organization for a minimum of three years following termination of DHEW support of the activity.

Section 46.63 *Reports*. Each organization with an approved assurance shall provide the Secretary with such reports and other information as the Secretary may from time to time prescribe.

Section 46.64 *Early termination of awards; sanctions for noncompliance*. (a) If, in the judgment of the Secretary, an organization has failed to comply with the terms of this part with respect to a particular Federal activity, he may require that said grant or contract be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) If, in the judgment of the Secretary, an organization fails to discharge its responsibilities for the protection of the rights and welfare of the subjects in its care, whether or not DHEW funds are involved, he may, upon reasonable notice to the organization of the basis for such action, determine that its eligibility to receive further DHEW grants or contracts or participate in DHEW assisted activities, involving human subjects, shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

(c) If, in the judgment of the Secretary, an individual serving as principal investigator, program director, or other person having responsibility for the scientific and technical direction of a project or activity, has failed to discharge her or his responsibilities for the protection of the rights and welfare of human subjects in his or her care, the Secretary may, upon reasonable notice to the individual of the basis for such action, determine that such individual's eligibility to serve as a principal investigator or program director or in another similar capacity shall be terminated. Such disqualification shall continue until it is shown to the satisfaction of the Secretary that the reasons therefor no longer exist.

Section 46.65 *Conditions*. The Secretary may with respect to any activity or any class of activities impose conditions, including conditions pertaining to informed consent, prior to or at the time of the approval of any activity when in the Secretary's judgment such conditions are necessary for the protection of human subjects.

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GUIDELINES FOR THE ETHICAL CONDUCT OF STUDIES TO EVALUATE DRUGS IN PEDIATRIC POPULATIONS

American Academy of Pediatrics
Committee on Drugs
1977

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AMERICAN ACADEMY OF PEDIATRICS

Committee on Drugs

Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations

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The U.S. Food and Drug Administration is the regulatory agency charged with the responsibility of certifying that drugs* are safe and effective for use as claimed. According to the FDA regulations, only 25% of the drugs currently marketed in this country can be advertised as safe and effective for children. This does not imply that the drugs are contraindicated or disapproved for use in infants and/or children; it only means that sufficient data have not been forwarded to the FDA to grant approval status for pediatric indications or uses. Because neither the safety nor the efficacy of many of these drugs is known for children, physicians have had two choices:

1. Avoid the use of the drug, that is, deprive children of the potential benefits of the therapeutic agents available to others.
2. Prescribe the drug despite the lack of FDA certification for children.

The American Academy of Pediatrics, through its Committee on Drugs, issued *General Guidelines for the Evaluation of Drugs To Be Approved for Use During Pregnancy and for Treatment of Infants and Children*[1] in 1974. The publication of these general guidelines and their implications for future drug development led the FDA to request that the Academy's Committee on Drugs advise it about standards of ethical research which could be recommended to assure that children, and society in general, are served appropriately by studies carried out in pediatric populations without undue hazard or discomfort. This document is the result of intensive deliberation by the Committee on Drugs, its consultants, and advisors about the ethical questions pertaining to clinical pharmacologic studies in infants and children.

The Committee recognizes the problems inherent in investigations on children, who lack legal authority to consent, and the risks inherent in obtaining third party consent. This document presents guidelines, not regulations, which are intended to offer a spirit and an approach to drug investigation in children. These guidelines should be studied and considered by investigators who do not fall under the regulations of the Department of Health, Education and Welfare, as well as by those who do. Review mechanisms are proposed to assure that investigators receive outside ethical scrutiny and that the intent of the guidelines has been met.

Most of the debate about the ethics of drug research stresses risks; however, in most research studies risks are minimal although the child may suffer inconvenience and discomfort as a result of enrollment in the study. Moreover, benefits are frequently derived from participation in clinical research studies. These benefits include closer medical scrutiny, better nursing attention, and more effective therapeutic interventions as a result of rigorous and scientifically valid protocols.

Experimentation Versus Research

Experimentation may be defined as the use of unproven methods, medications, or doses. Unproven therapies, while they may be called "innovative treatment," are actually experimentation, but they are not necessarily research. Research is well-controlled, systematic investigation intended to develop new and useful knowledge.

The Committee believes that it is unethical to adhere to a system which forces physicians to use therapeutic agents in an uncontrolled experimental situation virtually every time they prescribe for children. Furthermore, it is not only ethical but also imperative that new drugs to be used in children be studied in children under controlled circumstances so the benefits of therapeutic advances will become available to all who may need them.

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*Devices that carry therapeutic claims, antiseptics, cleansing materials, and other substances which may come in contact with children should be considered in the same manner as drugs when they are evaluated for use in pediatric populations. The same careful scrutiny must be given to the protocols under which such devices and agents are studied as outlined in this document for drugs.

The Need to Study Children

Children must be studied to make rational drug therapy available to themselves and to other children. Systematic research on new drugs must be carried out in children because no animal or clinical model exactly predicts the effect of agents on children of various ages and stages of development. Thus, the different volume of the various body fluid spaces in the early stages of development, the dynamics of growth of various organs, the changes in renal and metabolic function throughout infancy and childhood, and the myriad other alterations which are a part of normal human development may all modify the rate of elimination of the drugs, the dosage regimen, the effectiveness, and the safety of pharmacologic agents. Data obtained in animal models are inadequate, as is extrapolation from experience in adults.

The crucial experimental research from which the most important information can be obtained on the use of drugs in children is that which utilizes the child as the experimental subject.

Studies should be carried out in children by qualified investigators as soon as possible after the need for use in pediatric patients has been identified and basic pharmacologic information has been accumulated.

Pediatric patients should be selected as subjects for studies when there is a need for the results of studies in infants and children for therapeutic uses. In general, pediatric patients should be selected only after the safety and efficacy of the agent under study has been evaluated in adults. Efficacy data cannot always be obtained in adults, however, since there are situations in which therapy must be tested for the prevention or treatment of conditions peculiar to certain pediatric ages, e.g., kernicterus. Prior to recruiting children as subjects in clinical studies, data on absorption, metabolism, toxicity, and so forth should be available from adults. (Certain agents may be expected to have frequent and severe side effects and cannot be tested in normal volunteers. Thus, an antineoplastic agent to be tested for efficacy against a child's tumor may have to be tested in children without prior studies in adults.)

The Need for Ethical Guidelines

Standards for performance of clinical pharmacologic research in infants and children must be established with the same humane purpose and scientific objectives as standards for clinical practice. Ethical practice requires that treatment modalities available to others be made available to pediatric patients, and that, as for other subjects, appropriate protection be given to pediatric patients when they receive treatment. Poor scientific design or uncontrolled experimentation is unethical.

Ethical, as well as scientific, guidelines are needed for the evaluation of drugs to be used in infants and children and for the development of acceptable clinical research patterns for drug investigations in children. These patterns, when developed by medical-scientific, legal, and social experts (in consultation with informed laymen), will become widely accepted in time and may eventually be acknowledged legally, much as standards of practice activity are accepted by society and legally recognized.

These guidelines have been prepared because there is a need to assure that a balance is maintained between the protection of individual children; the accepted needs of a specific child, group, class of children, or society at large; and societal values in general.

CHARACTERISTICS OF AN ETHICAL INVESTIGATOR

Any proposal for clinical investigation must place the interest of the child first and must satisfy the following basic conditions.

1. The research proposed must be of value to the pediatric population in general and, in most instances, to the child subject.
2. The research design must be appropriate for the stated purposes.
3. The investigator must be competent and must understand the ethical issues involved in drug investigations in children.

The competence and ethical nature of the investigator is the most important safeguard for the protection of the interests of the child subject. The investigator must strive to obtain as much information as possible about the safety and efficacy of the drug under study prior to enrolling child subjects in the study. He/she must acquire a thorough knowledge of all relevant animal data and all phase I and early phase II tests in humans. In addition, he/she must have complete information about the known side effects of analogous or similar drugs and the age-dependent factors that may influence the activity of the drug under study in the subject *prior* to beginning studies in children. He/she should be required to demonstrate this knowledge in the proposal, in the construction of the protocol, and in a presentation to the institutional review committee.

An investigator should make every attempt to appreciate the feelings of all parties concerned prior to attempting to enroll subjects for study. He/she is responsible for assuring that all colleagues and associates in the proposed project are equally informed and have similar appreciation of the feelings of those involved. In addition to planning and administrative ability, the investigator should be sensitive to the feelings of individuals of different ethnic, racial, and socioeconomic backgrounds. Investigators should also attempt to understand the fears, concerns, and feelings of the child subjects. This understanding is especially important in pediatric studies because children may be unable to communicate their feelings and fears.

The investigator should also endeavor to understand the attitudes of the individuals qualified to act on the child subject's behalf. This is especially difficult and trying when the subjects are handicapped children, because the emotional reactions and motivations of those acting on behalf of these children may be complex. The feelings and attitudes that must be considered include those concerning pain, trauma, and hospitalization, as well as those concerning the racial, ethnic, and socioeconomic implications of being considered for and consenting to participation in a research study. Toward this end, studies carried out in children should be designed with input from a physician (or physicians) trained and experienced in pediatrics to insure maximal sensitivity to children's feelings and fears. The planning of studies in handicapped children should involve input from a physician experienced in dealing with handicapped children and their parents. The racial, ethnic, or socioeconomic characteristics of the children must be considered in designing the study, and the design must include input from appropriate community representatives.

Pediatric investigators must be acutely aware of possible conflicts between their own interests, the "need to know," and the interests of child subjects. The "need to know" must always be subservient to the needs of the child and his family. The investigator cannot be free from bias or self-interest, but he/she must strive to present a balanced view of the risks and benefits of the study when seeking informed consent from the individual acting on behalf of the child.

The ethical investigator recognizes the possibility that his/her own passion and bias may influence the decision and the presentation of the facts. It is important that he/she be self-analytical and seek insight into the bias of his/her own behavior and attitudes in planning and carrying out studies in children. When evaluating proposals, the institutional review committee must determine whether each investigator has considered these factors. When indicated, the institutional review committee should point out areas that must be reconsidered for the protection of child subjects.

ETHICAL ISSUES IN DRUG INVESTIGATIONS IN PEDIATRIC POPULATIONS

Basic ethical considerations for human studies have been evolved at various legal, medical, scientific, governmental, and human rights levels. However, there are also special considerations which apply to children. Children may be easily influenced and are generally regarded as requiring guidance and protection against exploitation. They may even require protection against their own actions, which may be contrary to their self-interest.

The major areas of concern in pediatric investigation include (1) determination of benefits and risks, (2) selection of subject groups and individuals, (3) obtaining informed consent, and (4) payment for participation.

Determination of Benefits and Risks

Research studies may be undertaken when they can be shown to be advantageous to the child or other children, and when the potential benefits are greater than the potential risks. The evaluation of benefits and risks of studies involving children must be based on the broadest and most comprehensive view.

The benefits of the proposed study must be assessed prior to an evaluation of risks from the study. *Studies that promise no demonstrable benefits should not be conducted, irrespective of the minimal nature of the attendant risks.* Benefits should be construed broadly in an evaluation that takes into account the importance of developing new treatment modalities for children in general, for the class of children represented by the child subject, and, as appropriate, for the subject's own future interest and benefit. Furthermore, the benefits of participation in the study have a significant bearing on the ethical nature of the proposal and must be recognized in this evaluation. The introduction to these guidelines mentioned several benefits which could accrue to a child subject in the conduct of controlled studies, which require observations and careful attention to many details for scientific purposes.

Children should be permitted to participate in a carefully monitored study with minimal risk and maximal protection under some conditions, if the study promises broad scientific benefit to society at large or to a group of individuals. Any assessment of a benefit-risk relationship must take into account the seriousness of the condition being treated with the research drug; the likelihood of benefit to the individual, the class of patients under study, and children in general; and the risks of the proposed study.

Inherent risks of the proposed study must be evaluated in the broadest context. These risks include the known and predictable effects of the drug as determined from animal studies, prior studies in adults or children, or observations from clinical practice with children.

The potential for psychologic and social damage or dislocation and the possibility that some effects may remain latent for many years must also be weighed in assessing the ethical nature of a proposed study. Studies to be carried out in children must be scrutinized for potential risks that are not usually of concern when considering studies in adults. Some of the risk factors in proposed studies in children, in addition to discomfort and inconvenience, may be pain, fright, separation from parents, and separation from familiar surroundings.

Risks and fears should be minimized by limiting the number and type of invasive tests in the study. However, an invasive procedure is no less ethical per se than other procedures. Rather, the entire study, including all proposed procedures, must be weighed in determining its ethical qualities.

Requiring a child to submit to venipuncture so a blood sample can be obtained when studying the half-life of a new drug must be evaluated in the light of available technology for determining the concentration of the drug in biologic fluids. It might be unethical to do a venipuncture to obtain blood when a fingerstick for blood or a urine sample would provide sufficient information; however, it is definitely unethical to give more of the drug than absolutely necessary only to avoid doing a venipuncture, if available methodology requires higher doses to obtain the data from capillary blood or urine specimens.

Selection of Subject Groups and Individuals

General Considerations. Subjects enrolled in clinical investigation should represent a cross section of society insofar as possible. The study should not rely exclusively or heavily on one socioeconomic, racial, or ethnic group when this type of selection is not a necessary part of the investigation. The institutional review committee must be uniquely sensitive to this principle and ask, "Is there an equitable distribution of risks and inconveniences of this investigation throughout all societal groups?" This is especially important when the study group will be drawn from an institution or community frequented mainly by one socioeconomic, racial, and/or ethnic group. The institutional review committee must consider whether one group from the population at large will bear an undue portion of the burdens or will be able to avail itself of an undue portion of the benefits if the research is conducted at only one institution. If there is an imbalance, the institutional review committee must ask whether other population groups can be added to the study in the same community, as well as whether a multicenter program could distribute the risks and benefits more appropriately without adversely altering the study design. When studies are conducted at only one institution, ethical practice requires that a reasonable cross section of all groups in the community participate.

Special Considerations. Institutionalized retarded children and other children who are confined in a residential facility may be selected as subjects of a study only if the study involves situations or conditions peculiar to these individuals and the information sought can only be obtained from their participation. Special safeguards may have to be provided to assure that appropriate consent is obtained for these children's participation (see below).

Obtaining Informed Consent

General Considerations. No drug research may be performed in humans without the informed consent of the subject or of an individual legally qualified to act on behalf of the subject.

The right of a patient to consent or to withhold consent for an investigational procedure or therapeutic intervention on an informed basis is well established in ethics and law. It has been incorporated in the Nuremberg Code, the guidelines of the American Medical Association, the Declaration of Helsinki of the World Medical Association, and government regulations.

The requirement for informed consent for participation in a research study raises many questions, especially when minors are subjects of proposed research. Among these questions are "When is the administration of the drug considered a part of a research program?" "How informed is informed?" "Who can consent on behalf of the child?" "At what age is it also necessary to seek the consent of a minor?" "At what age is it important to also have the assent of the minor?" "What mechanism is available to assure adequate protection of the child subject?"

The following material contains guidelines for obtaining informed consent for drug research in infants and children and a discussion of some of the underlying ethical principles. These guidelines are not specific to all situations. Their interpretation is the responsibility of local institutional review committees, which may wish to develop independent subgroups to respond to specific questions and represent the child and other appropriate interests.

Who May Consent? Consent for drug research in children must always be obtained in writing from an individual legally qualified to act on behalf of the child (usually a parent or guardian). In some instances, "emancipated minors" who are legally and ethically qualified to give consent for themselves without the consent of another individual may be the only consentors required when they participate in studies. In general, it is advisable that consent be obtained both from the child subject, when he/she is at least 13 years old, and from an adult acting on the child's behalf. In general, before the study is implemented, assent (agreement to participate) should be obtained from any child who is at least 7 years old when the individual acting on his/her behalf has given consent (see below).

Consent should always be based on free choice. It is not ethical to obtain consent on the basis of coercion, inducement, or reward. Furthermore, the ethics of obtaining consent require that the consenting individual(s) be informed about the nature of the study, its goals, the risks involved, the benefits to be expected, and the provisions made to safeguard the welfare of the child subject.

Informing the Consentor. Information provided to the subjects and/or the individuals acting on their behalf must be written and in a language that can be understood by them. The ethics of informing the potential subjects of an investigation of the nature of the study, and of the risk-benefit equation do not require "total" or "full" disclosure. However, all significant and reasonably expected consequences must be enumerated and explained, and the consentor must be directed to and have full access to individuals qualified to answer all of their questions.

The institutional review committee is responsible for the supervision of the procedure by which the prospective consentor is informed. It must assure that the investigators and/or their representatives do not coerce, entrap, or bias the consentor. The institutional review committee must specify the minimum amount of information required in a proposed study for valid "informed" consent to be obtained. The amount of information given under a research protocol must be decided on by the investigator in conjunction with the institutional review committee, the members of which are assumed to be reasonable individuals acting in the best interests of the prospective subjects. In no instance should investigators withhold any information from the potential consentor(s) unless they have prior approval to do so.

Different information may be required by the institutional review committee for one research project than for others. The facts to be presented to the subject or those acting on the subject's behalf will be determined in each study by the nature of the study and the type of research proposed. In some instances a system for "surrogate" review may be required to clarify the subject's "need to know" before deciding whether to consent to enroll a child in a study (see below). This provides safeguards to assure that the individual acting on behalf of the child is indeed acting in his/her best interest, with full information concerning the potential risks and potential benefits of the proposed study.

Potential child subjects of a research study are entitled to several sources of protection. One source is the investigator who proposed the study. Any individual proposing research in children must be willing to accept a child advocacy role as well. Other sources of protection are the child's parents or guardian (or someone else acting on his/her behalf) and professionals other than the investigator—at least some of whom should also be drawn from groups including child advocacy in their professional principles. Members of the child's community must also participate in the protection of the child during the planning and organizational review stages of any project involving child subjects.

Consent From Minors. Children at certain ages are entitled to participate in determining what is in their best interest.

Subjects 13 years of age or older must be informed and give their informed consent to be enrolled in research studies, unless the institutional review committee agrees that they are not competent to do so. It must not be inferred that children of this age have the right to refuse therapy deemed necessary for their well-being, but only that they have the right to refuse to participate in the research aspects of any protocol in which they have been entered. The minors must be provided with all relevant information prior to being asked for a decision about consent, but they may be informed at a different level of sophistication than the adult legally consenting for them.

In all instances the adult legally acting on behalf of the minor must consent before the minor is approached for his/her consent. In some instances the institutional review committee may agree with the investigator that the age at which consent is required for certain studies should be higher than that stated here, and the investigator may enroll child subjects under a research protocol without their consent even if they are more than 13 years old. Such exceptions can only be made with the agreement of the institutional review committee, and they must be based on a determination that the child's best interest would not be served if his/her consent were sought or if he/she were given enough information to reach a conclusion about consent. Factors such as the nature of the disease to be treated, the state of consciousness of the child, and the psychologic impact of certain information on child subjects may be presented when exceptions are proposed.

Assent From Minors. Assent should be obtained from any child 7 years of age or older after the individual acting on his/her behalf has given consent and before he/she is enrolled in the study. For the purposes of these guidelines, assent is defined as the agreement to participate in a research study (or to have specimens collected) by a minor not qualified to give consent but who has reached the intellectual age of 7 years. When the intellectual age of the individual cannot be approximated, a chronologic age of 7 years can be assumed to be required for assent. This protection permits a child older than 7 years to say "no" to involvement in any studies or procedures done for research purposes.

There may be instances when it is not in the child's best interest to assent to participation in a research study because of the stressful nature of the information required to answer questions about the reasons for participation. In such instances, the institutional review committee must review these special conditions and agree with the investigator's assumption that obtaining the assent of the subject would be detrimental to, or at least not in the best interest of, the child subject before approval can be granted. In all such instances, the institutional review committee must be given the authority to make the final decision, or to establish a mechanism through its operating policies and procedures to decide whether the research may proceed.

Payment for Participation

It is in accord with the traditions and ethics of our society to reward people who do something for us or who participate and cooperate with us in achieving our goals. However, serious ethical questions arise when payment is offered to adults acting on behalf of minors in return for allowing minors to participate as research subjects. Although there are altruistic and other incentives inherent in offering to become a research subject, external incentives must be avoided and payment or other material benefits should not be large enough or of a nature to induce responsible persons to agree to allow a dependent to participate in a study or to subject them to painful or invasive procedures. This principle places major burdens on the pediatric investigator and the institutional review committee.

Remuneration. Remuneration beyond token gestures of appreciation for participation should be avoided. If remuneration is provided, it should not be of a nature to become an incentive. The waiver of medical costs associated with treatment under a research study may be permitted in certain circumstances. The institutional review committee should review any proposed remuneration to assure that the possibility for coercion has been minimized.

Compensation. The investigator may make funds and facilities available to reimburse the child (or the family) for any costs incurred because of the child's involvement in the study. The institutional review committee must ascertain that the compensation offered is fair and does not become an inducement for the consentor to agree to the participation of a child subject.

Indemnification. There are standard protections against negligence by professionals or health care institutions engaged in research. However, an additional mechanism must be available to indemnify subjects and their families on a "no-fault" basis for any untoward occurrences resulting from the study. Thus, it is incumbent upon institutions carrying out investigations to assure that some form of indemnification is provided and that the individuals legally acting on behalf of child subjects are aware of this coverage.

When untoward reactions occur during a study, the institution and its investigators are obliged to provide medical care free of charge so the subject can be returned as nearly as possible to his/her prior state of health.

Withdrawal From Study

The adult consenting for a child subject and the consenting minor must be informed of their option to withdraw from the study at any time.

They must be informed that withdrawal will not jeopardize the subject's access to care. Investigators should not make coercive statements or try to influence the subject with incentives when the consentor decides to withdraw a subject from a study. Institutional review committees and investigators should be especially alert to departures from ethical practices when there is a possibility that a child may be removed from a study.

SPECIAL POPULATIONS

The Retarded Child

Children who are retarded have the right to protection from bearing an undue portion of research studies. The noninstitutionalized retarded child is entitled to the same protections available to other children and, as is true of other children, has a right to be considered a participant in the process and benefits of research studies conducted according to these guidelines. Because certain diseases, clinical problems, and behavior patterns are found principally or exclusively in children who are retarded, and because responses to certain drugs may vary considerably in them as opposed to other children, some studies may have to be limited to child subjects who are retarded. However, any claims about this requirement must be scrutininzed by the institutional review committee to assure that the principles outlined here concerning the need to distribute research benefits and burdens have not been ignored.

The Institutionalized Retarded Child

Institutionalized retarded children are entitled to benefits that may accrue as a result of research on conditions and situations related to their status. However, parents and other individuals who are legally qualified to act for a child may not necessarily act in the child's best interest when the child has been institutionalized. If other methods to obtain information of direct benefit to institutionalized retarded children are not available and research involving these children as subjects is proposed, the institutional review committee must be especially careful when reviewing the mechanisms for protection of the retarded minors.

One mechanism to assure that special protection is provided for institutionalized retarded individuals would be the use of an "advocate group" consisting of several parents of children in the institution, physicians, lawyers, clergy, and others as appropriate. If this group is established, it should be independent of the investigator and of the institutional review committee. It should be charged with the evaluation of risks and benefits from the child's point of view and be asked to pass on the appropriateness of the proposal after its scientific validity has been established by the institutional review committee and before the proposal is presented to the person acting on behalf of the individual child. The "advocate group" should have "veto" authority over the conduct of a study at the institution and over the enrollment of individual children into the proposed study group.

Institutionalized children may never participate in research involving drugs which are not given for their direct benefit.

Nonretarded Institutionalized Minors

Another group sometimes considered for research studies is made up mainly of youngsters institutionalized under the supervision of a court or a social welfare agency (either public or private) acting in lieu of a court. These children lack the special characteristics of the retarded and, in general, are subject to disease processes similar to noninstitutionalized children. Because institutionalization deprives these minors of some of the safeguards necessary for the conduct of ethical investigations, they should rarely be considered for inclusion in research studies. In general, members of this group should only be involved in studies of specific conditions found predominantly in them or in this type of institution. Institutionalized minors should also have access to experimental drug therapy under a research protocol when that therapy is the only treatment available for the disease from which they may be suffering. When institutionalized minors are considered for inclusion in research studies, the safeguards stipulated for institutionalized retarded children should also be afforded to them.

INSTITUTIONAL REVIEW COMMITTEE (COMMITTEE ON HUMAN EXPERIMENTATION)

Any institution under whose auspices clinical research is conducted must assure that the investigation is reviewed by an appropriately constituted institutional review committee. When clinical investigations are to be conducted in children by individuals independent of institutions with such a committee, a review committee which will serve the same function as the institutional review committee should be established to assure that the proposed investigations are carried out within accepted guidelines and are subjected to appropriate ethical scrutiny.

The institutional review committee affords protection for the subject, for the institution, and for the investigator. The institutional review committee should be composed of medical scientists, other physicians who are not engaged in clinical investigations, representatives of the community, and nonmedical professional groups.

All committees reviewing proposals for investigations in children must include persons who care for children. These persons are likely to be more aware of the special psychologic and social needs of child research subjects and are likely to be better advocates for children's welfare. It may be advisable for institutions to have a separate subcommittee with medical representation composed predominantly, if not exclusively, of pediatricians to review and approve proposed protocols which involve minor subjects.

The following is an example of minimal procedures for review of pediatric proposals: The first review of a proposal submitted to the committee should be undertaken by a primary reviewer who is a member of the committee. This individual should review the entire protocol in detail with the investigator, then assume the role of informed participant in the committee's thorough review of the proposal. The primary reviewer can discuss with the committee his/her determination of the adequacy of the risk-benefit evaluation by the investigator, the appropriateness of the proposed procedures, the amount of information to be given to the consentor, the protections afforded to the subjects, and the ethics of the proposal in general. The primary reviewer should be responsible for assisting the investigator in his/her preparation of the proposal and the consent document to assure that both fit within the guidelines established by the committee for investigations in children. The primary reviewer is, therefore, charged with the responsibility of acting as the committee's representative to protect the rights and welfare of the subjects.

After a proposal is approved, the primary reviewer should act as a monitor and maintain contact with the investigator and institutional personnel who are aware of the nature of the study and its conduct. This will provide an additional safeguard to protect the child's welfare and ensure that there is no deviation from the rigorous ethical requirements approved by the committee.

The institutional review committee should establish a mechanism to assure that no child is enrolled in more studies than is consistent with his/her welfare. The nature of pediatric clinical studies is such that there may be reason to seek to enroll the same child in more than one study at the same time. In most instances this does not jeopardize the child's welfare or safety, but in some situations the child's participation in more than one study may be to his/her detriment. To protect the scientific integrity of his/her project, the investigator should know if his/her subjects are involved in any other research projects, and the institution must assure that this information is available. Thus, the institutional review committee might request advanced information of plans to enroll specific individuals into study protocols so it can be determined if enrollment in this project would be contrary to the interest of a child enrolled in another research study.

DRUG RESEARCH

General Considerations

Therapy is the treatment of a disease. Drug therapy is the use of drugs (as opposed to physical or psychologic means) for the treatment of disease. Thus, if therapy with a marketed drug is used by a physician solely for an individual's benefit, it should not be considered research, even if the drugs cannot be advertised for this indication or purpose. However, if drug therapy is used by a physician for the acquisition of knowledge which may be of benefit to others, as well as for therapy, it is research (albeit research in a therapeutic situation). This type of research is subject to the ethical and medical scrutiny proposed here.

Drug research may be divided into two major, but not mutally exclusive, categories: research under therapeutic conditions (type I research) and nontherapeutic research (type II research). Type I research includes studies of the safety, elimination, metabolism, efficacy, and interactions of drugs given to treat a condition or illness. Type II drug research involves studies on drugs given principally to determine their effect and action unrelated to therapy of the individual. Because these major categories involve different ethical and medical considerations, different protections may be required for the subjects of each type of research.

Research Under Therapeutic Conditions (Type I Drug Research)

There are several subcategories in type I drug research.

1. Noninvasive studies that do not include an additional pharmacologic agent to a prescribed treatment regimen. *Example:* The patient is given a well-established therapeutic agent for his illness. The investigator studies the metabolism or excretion of the drug in the patient's normal excretory products (e.g., urine, sweat) or observes

the patient's behavior, response, or condition after administration of the drug.

2. Invasive studies that do not involve an additional therapeutic agent. *Example:* The patient is being given a drug which is the established form of therapy for his illness, but the investigator wishes to procure several blood specimens to establish the kinetics, absorption, and so forth of this drug in the patient's age group.

3. Studies of the efficacy, safety, and dose of an investigational drug in children. *Example:* (1) A drug effective for a condition in adults is to be tried for treatment of a child with a similar condition. The investigator wishes to determine the efficacy of this drug in children with the condition, its safety for the developing organism, and the appropriate dose and dosage regimen for its administration in a child. (2) An agent with potential value in animals or laboratory studies for a condition occurring only in infants and children (e.g., respiratory distress syndrome or infantile spasms) is to be administered to a child subject with this condition to establish pharmacologic parameters, such as safety, efficacy, and metabolism, in the absence of comparable data in adults.

The Committee on Drugs believes that drug studies in infants and children should include detailed evaluations of the pharmacology of the drugs in the various age groups, but there is at least one exception to this requirement. In the foregoing situation, where a disease or condition occurs only in infants and children, it may be reasonable for pilot studies of the efficacy of an investigational drug for the condition to proceed after only minimal pharmacokinetic studies. If pilot studies indicate probable efficacy, the ethics of drug evaluation in children require that an investigator's protocol incorporate detailed research into safety, efficacy, and general pharmacology in succeeding studies.

Whenever possible, research protocols should be designed to permit the results of laboratory studies to be used for the benefit of the research subject. This is especially important in studies of investigational drugs in children; the ethical nature of such studies is clearest when minor subjects can derive benefit from the use of the investigational drug as well as the various tests done as part of the scientific investigation.

4. Studies requiring the use of placebos. In general, placebos should be used when data cannot be obtained by comparing the efficacy and safety of the drug under study with either a commonly used therapeutic agent for that condition or the natural course of the disease as described from clinical studies. The work "placebo" is not intended to mean "untreated" because any routine treatment must continue in all drug research in children where placebos are used. The conditions under which the use of placebos is ethical in drug research in children include (1) when there is no commonly accepted therapy for the condition and the agent under study is the first one that may modify the course of the disease process; (2) when the commonly used therapy for the condition is of questionable or low efficacy; (3) when the commonly used therapy for the condition carries with it a high frequency of unacceptable side effects; (4) when the incidence and severity of undesirable side effects produced by adding a new treatment to an established regimen are uncertain; (5) when the disease process is characterized by frequent, spontaneous exacerbations and remissions.

5. Long-term prospective studies of the safety of a drug. When drugs are administered to developing organisms, the effects may be latent for a long time and cannot be predicted from any prior studies or experience. *Examples:* (1) A drug used in pregnant women must be studied for its effect on the fetus. Follow-up studies of the offspring must also be done to determine if there are late effects. (2) Studies of drugs effective for therapy of acute conditions which are given to pediatric patients over a short period of time require some mechanism for follow-up and evaluation of the research subjects.

Even a brief period of drug administration at a critical period in the development of an individual might lead to long-term effects on behavior, learning, and so forth. Planning pediatric drug research is especially difficult when it involves long-term administration of an agent for chronic managment of a disease process (e.g., hyperactivity or asthma). Evaluation of the long-term effects on learning, behavior, respiratory function, and other processes must be built into the original design of the study. In long-term prospective studies in children, the drug's action may interfere with cell metabolism, e.g., as with the chemotherapeutic agents used in neoplastic and unremitting viral diseases. Therefore, there must be some mechanism to determine such possibilities as development of new forms of neoplasia at a later age, disturbance of learning processes and other central nervous system functions, or serious compromise of growth and behavior patterns. Thus, even if a new therapeutic agent is life-saving, the ethics of drug evaluation in children require the investigator to look at the effects of the new drug on the quality of life following treatment and compare them with the effects of other forms of therapy.

Nontherapeutic Research (Type II Drug Research)

1. Studies of the pharmacology and toxicology of drugs (1) taken accidentally or in overdoses in infants, children, or pregnant women; and (2) which enter the fetus or newborn infant transplacentally or through breast milk because of necessary therapeutic use by the pregnant woman or nursing mother. *Examples:* (1) A child ingests a drug prescribed for another person's use. (2) A child is overdosed with a prescription drug or an over-the-counter preparation whose pharmacology and toxicology have not been established in children. (3) A pregnant woman ingests a drug or is given a drug for an illness, and the effect on her fetus is unknown or uncertain. (4) A lactating woman ingests or is given a drug without knowledge of the effect of the drug on the developing infant.

When type II studies are to be conducted after accidental intake of a drug, the conduct of the study may not in any way interfere with the appropriate treatment of the patient's acute condition.

2. Prospective studies to advance knowledge for the future benefit of the child subject. *Example:* A youngster with cystic fibrosis is given a few doses of a new antibiotic so investigators can learn about its pharmacology, despite the fact that he has no infection requiring its use at the time it is administered. This type of study is within the ethical framework stressed in this document *only* when the results of the research can be predicted to lead to more effective and safer therapy of the same individual when this type of treatment is indicated.

3. Prospective studies to advance knowledge for others. In general, the Committee on Drugs believes that it is not ethical to conduct studies which offer no benefit to the child subject.

However, such studies might be ethically permissible with agents that are available over the counter in the dose and form to be given since such drugs might in any case be in general use. When this type of study is to be carried out, there must be consent from the person acting on behalf of the minor and, except as specified here (at least), assent from the minor himself/herself. If the studies entail an excess of pain or discomfort for the age group in question over that associated with usual hospital or clinic procedure, they can be carried out only in individuals who have reached the age when consent can be obtained from them as well as from the adult acting on their behalf. When procedures necessitated by the study of over-the-counter drugs will not impose pain or added discomfort, children who are old enough to assent may be considered as subjects. When the procedures will not impose pain or added discomfort and there are data from prior common use concerning the safety of the drug at the dose proposed in the protocol, children below the age of assent may be enrolled in such studies.

Ethical Considerations

Type I Drug Research.

1. Noninvasive type I drug research studies should not pose problems for ethical review. Nevertheless, informed consent must be obtained before this type of study is carried out.

2. Invasive type I drug research studies need not cause problems for ethical review, if the data to be generated will assist in the treatment of the child under study. However, when this type of study does not assist in the treatment of the child, the institutional review committee must give special attention to the proposal. It must ascertain that any risks are weighed appropriately against the benefits others may derive from the results of the study. In these instances, the consent of the child 13 years or older or the assent of a child between 7 and 13 years of age should be required in addition to consent of the person acting for the child before he/she is enrolled in the study.

3. Studies of the efficacy, safety, and dose of investigational drugs in children may only be carried out in infants and children with the disease or condition for which the drug is to be tested. When agents are used for conditions occurring only in children (e.g., respiratory distress syndrome), the institutional review committee must review the safeguards provided for the subjects with unusual care. Every attempt must be made to have laboratory evaluations of the progress of therapy available to the physician responsible for the patient's care soon enough to be useful clinically. Any systems known to be adversely affected by the agent in adults (from phase I studies) should be monitored carefully.

4. When placebos are to be used, the subject or someone acting in his/her behalf must be fully informed about the nature of placebos, the design of the experiment, and the reason for the inclusion of a placebo group. Efforts must be made to design the protocol to minimize risks and trauma to the child who may not be receiving the active drug. Furthermore, the protocol should be designed so the active drug will be introduced into the study regimen for each subject at the earliest possible time.

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5. It may not always be possible to complete the long-term follow-up studies suggested here. However, the investigator must provide a plan for follow-up studies prior to the enrollment of subjects. Furthermore, the subjects and the persons acting on their behalf must be informed of this requirement at the time consent is obtained. Investigators are ethically obliged to fulfill this commitment to the subject and society; it is an implied commitment when he/she accepts the privilege of carrying out investigations in children.

Type II Drug Research (Nontherapeutic).

1. Studies of drugs taken accidentally, in overdose, or via the placenta or breast milk are important in gaining information on the pharmacology and toxicology of drugs in normal infants and children. The accidental ingestion of a drug or the accidental overdosing of a patient provides an unusual opportunity for study of drugs in normal children. It is "unusual" because normal children cannot be used for "phase I" testing and because no individual may ever intentionally be given more than the usual therapeutic doses for study purposes.

The study of this type of patient is an ethical form of opportunism; it may not be of direct benefit to the subject but may be of enormous benefit to others. Protocols to carry out such studies should be designed, approved in advance, and evaluated carefully by the institutional review committee so they can be kept on file and activated when the opportunity presents itself. The institutional review committee must be especially critical of such protocols to assure that "the need to know" for others does not expose the subject to undue trauma or risk.

2. Detailed conditions under which prospective pediatric drug studies to advance knowledge for others may be carried out have been discussed.

SUMMARY

To be acceptable, protocols for clinical pharmacologic studies in children must meet high ethical and scientific standards. Any study that is unacceptable medically or promises no significant scientific benefit in its aims or construction is unethical by definition. Studies believed to be medically and scientifically acceptable must then be scrutinized carefully to determine that the risks are minimal when compared with the benefits and that the individual child is as well protected as is reasonable. Only then may a study be considered accepted as ethical and approved for implementation.

Investigators who wish to carry out drug studies in children should be acquainted with the ethical requirements of such investigations in children. Informed consent should be obtained from an adult acting on behalf of the minor in all instances prior to the enrollment of a child into a study. The investigator's zeal should not be permitted to result in misrepresentation of the nature of the study. Assent by the child is essential for children more than approximately 7 years of age. The child should be old enough or intellectually mature enough to be capable of understanding appropriately presented data about the study and the procedures required if he/she enrolls in it. These children should be given the right to say no, even when an adult acting on their behalf has given consent. Minors 13 years of age or older may be enrolled in a study only after they have been appropriately informed and have given their consent.

Frequent review of the progress of the activities of the institutional review committee and of the implementation of approved proposals is required for the protection and welfare of children enrolled in studies. Similar review is required when drug investigation studies are carried out in children in the absence of institutional supervision. Continuing review provides a mechanism to maintain the highest ethical standards.

These guidelines are designed to provide a format allowing for maximal protection of child subjects of drug research. The guidelines also acknowledge both the "need to know" and the "unethical" nature of the situation in which pediatric therapeutics finds itself today. It is hoped that these guidelines will pave the way for an increase in the number of drug investigations carried out in children, and thereby improve health care for all children in the future.

COMMITTEE ON DRUGS

Members: Sydney Segal, M.D., Chairman; Sanford N. Cohen, M.D.; John Freeman, M.D.; Benjamin M. Kagan, M.D.; Ralph E. Kauffman, M.D.; Marie I. New, M.D.; Albert W. Pruitt, M.D.; Lester F. Soyka, M.D.

Consultant: Sumner J. Yaffe, M.D.

Liaison Representatives: John C. Ballin, Ph.D.; Charlotte Catz, M.D.; Pierre S. Del Prato, Pharm.D.; Louis Farchione, M.D.; Martha M. Freeman, M.D.; Clifford P. Goplerud, M.D.; John A. Leer, Jr., M.D.; Godfrey Oakley, M.D.; Steven Sawchuk, M.D.; C. P. Scott, M.D.; Artemis P. Simopoulos, M.D.

Special Liaison Consultant: Alan K. Done, M.D.

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